



Sent by: Andrea
Govender/MOH
24/12/2014 09:44 a.m.

To: medsafe-l@listserver.actrix.co.nz,
cc:
bcc:

Subject: Prescriber Update 35 (4) - December 2014

Prescriber Update

Vol. 35 No. 4 December 2014

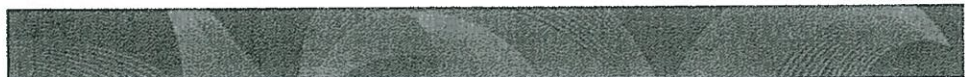
Click on the links below to access the full text of the articles included in the December 2014 edition of *Prescriber Update*.

This edition contains the following articles

[Use of Sodium Valproate in Pregnancy](#)
[Keeping Patients Informed about Colchicine Use](#)
[Tramadol – the Highs and Lows](#)
[Importing Medicines for Personal Use](#)
[Pump up Testosterone Levels Safely](#)
[MARC's Remarks: September 2014 Meeting](#)
[Can I Have a Drink with That?](#)
[Simvastatin Interactions and Fatal Reports](#)
[Quarterly Summary of Medsafe's Early Warning System Communications](#)
[Reporting Suspected Adverse Reactions Electronically](#)
M [MEDICINES MONITORING: Zoledronic acid Added](#)
[Prescriber Update Quiz 2014](#)

Click on the link below to access a PDF version of December 2014 edition of *Prescriber Update*.

[Prescriber Update 35 \(4\) December 2014](#)



RELEASED UNDER THE OFFICIAL INFORMATION ACT



Sent by: Susan
Kenyon/MOH
13/05/2015 09:25 a.m.

To: [REDACTED]
cc: Chris James/MOH@MOH,
bcc:

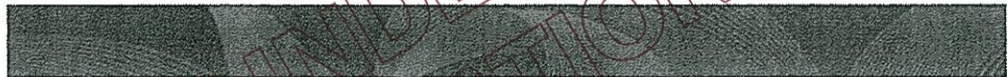
Subject: EWS- alert for Epilim

Hi
Please find attached an alert we propose publishing on Epilim.
There is no publication date at present as we are waiting for the company to finalise their additional educational materials.
Kind regards
Susan

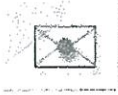


Epilim alert communication.docx

Susan Kenyon | Principal Technical Specialist - Pharmacovigilance | Clinical Risk Management |
Medsafe | Ministry of Health | [REDACTED]



RELEASED UNDER THE
OFFICIAL INFORMATION ACT



Sent by: Amanda
Taylor/MOH

29/09/2015 02:28 p.m.

To: medsafe-l@listserver.actrix.co.nz,
cc:
bcc:

Subject: Alert Communication: Use of sodium valproate (Epilim) in pregnancy

Medsafe Alert Communication

29 September 2015

Medsafe has published a new alert communication

Use of sodium valproate (Epilim) in pregnancy

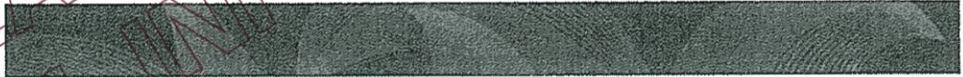
Read the alert communication at:

www.medsafe.govt.nz/safety/EWS/2015/sodiumvalproate.asp

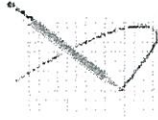
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OFFICIAL INFORMATION ACT



Sent by:

[Redacted]

To: [Redacted]

cc:

bcc:

16/07/2001 12:49 p.m.

Subject: Additions to Medsafe's Web site 9 July - 13 July 2001

Additions to Medsafe's Web site 9 July - 13 July 2001

<http://www.medsafe.govt.nz/indexie4.htm>

<http://www.medsafe.govt.nz/indexother.htm>

INFORMATON FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/emi/CMIForm.asp>

New - Cytotec, Danocrine, Diflucan, Diflucan IV, Epilim injection, Eryc, Glytrin, Micanol, Norflex, Pancrease, Reminyl, Resonium A, Somac, Vesanoid, Zithromax

Updated - Cellcept, Epilim, Relenza, Zenapax, Zyban

Datasheets - <http://www.medsafe.govt.nz/Profs/Datashcet/DSForm.asp>

New - Aciclovir, Bleomycin Sulfate, Cefuroxime Sodium, Cociois, Crystacide, Cytotec, Daunorubicin Hydrochloride, Dobutamine Hydrochloride, Doxorubicin Hydrochloride, Edetate Disodium, Haloperidol Decanoate, Naloxone Hydrochloride, Miflasone, Pacific Cefaclor, Phenoxymethylpenicillin, Zostrix

Updated - Avonex, Betaloc CR, Cordarone X, Flomax 0.4, Infanrix-IPV, Solu Medrol, Sporanox capsules, Sporanox oral solution, Trileptal, Visudyne, Zanidin

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette notice for 12 July 2001 added

28/02/2003 12:31 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 24-28 February 2003

Additions to Medsafe's Web site from 24-28 February 2003

INFORMATION FOR CONSUMERS

Support Groups - <http://www.medsafe.govt.nz/Consumers/support.htm>

The contact details for Diabetes NZ has been changed

INFORMATION FOR HEALTH PROFESSIONALS

Adverse Reaction Reporting and IMMP -

<http://www.medsafe.govt.nz/Profs/adverse/Minutes112.htm>

The Minutes of the 112th Medicines Adverse Reactions Committee meeting have been added

Classification of Medicines

The dates and deadlines have been updated -

<http://www.medsafe.govt.nz/Profs/class/dates.htm>

The Agenda for the 29th Medicines Classification Committee meeting has been added

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Lantus

Updated - Agenerase, Elocon, Epilim IV, Epilim tablets & syrup & liquid, Estraderm TTS, Flixotide accuhaler, Flixotide aerosol inhaler, Flixotide CFC-free inhaler, Gentamicin, Monofeme 28, Nizoral, Nordette 21, Nordette 28, Nordiol 21, Pegasys, Permax, Seretide accuhaler, Seretide inhaler, Serevent accuhaler, Topamax, Trifeme 28, Triphasil 28, Zyban

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 27 February 2003 has been added

Guidelines & Codes - New Zealand Regulatory Guidelines for Medicines -

<http://www.medsafe.govt.nz/Regulatory/Guideline/medicines.htm>

The contact details for the Chairman of SCOTT have been changed

Becci Slyfield

<http://www.medsafe.govt.nz>

[REDACTED]

To: [REDACTED]
cc: [REDACTED]
bcc:

07/03/2003 03:56 p.m.

Subject: Additions to Medsafe's Web site from 3-7 March 2003

Additions to Medsafe's Web site from 3-7 March 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Qvar autohaler, Qvar inhaler

Updated - Accuretic, Arcoxia, Epilim, Midamor, Nizoral, Noroxin, Singulair, Xenical

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apatef, Celapram, Cromolux, Dynastat, Fucifthalmic, Ledertrexate

Updated - D-Zol, Headway, Intragam P, Logoderm, Mabthera, Nicorette gum, Nicorette inhaler 10mg, Nicorette patch, Nicotrol, Nordiol 21, Noroxin, Plinzene, Progout, Pulmozyme, Roferon A, Spirotone, Staphlex, Tazocin, Trichazole

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 6 March 2003 has been added

Becci Slyfield

[REDACTED]

<http://www.medsafe.govt.nz>

[REDACTED]

[REDACTED]
17/04/2003 04:15 p.m.

To: [REDACTED]
cc: [REDACTED]
bcc: [REDACTED]

Subject: Additions to Medsafe's Web site from 14-17 April 2003

Additions to Medsafe's Web site from 14-17 April 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Recormon, Betaferon

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

Updated - Actilyse, Augmentin, Betaferon, Epilim, Fosamax, Lipex, Nordiol 21, Trental, Vioxx, Zeffix oral solution, Zeffix tablets

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

The Gazette Notice for 17 April 2003 has been added

Becci Slyfield

[REDACTED]
<http://www.medsafe.govt.nz>
[REDACTED]

OFFICIAL INFORMATION ACT
USED UNDER THE

17/08/2007 03:53 p.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 4-8 August 2003

Additions to Medsafe's Web site from 4-8 August 2003

HOT TOPICS

Media Releases - <http://www.medsafe.govt.nz/Hot/Media/2007/ANZTPA.asp>

The Therapeutics Products and Medicines Bill has been postponed

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Arava, Byetta

Updated - Crixivan, RotaTeq, Sumagran

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Prof/Datasheet/DSForm.asp>

New - Aquamid, Byetta,

Updated - Arava, Avandia, Crixivan, Dobutamine in 5% Dextrose, Epilim, Epilim IV, Fluvax, Invanz, RotaTeq, Solian

REGULATORY INFORMATION

Guidelines & Codes - <http://www.medsafe.govt.nz/regulatory/guidelines.asp>

Appendix 4: Checklist for New Prescription Medicine Applications (CTD) - effective from 17 August 2007

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.anztpa.org>

There are no updates to this site this week

Becci Slyfield

<http://www.medsafe.govt.nz>

RELEASED UNDER THE OFFICIAL INFORMATION ACT

28/11/2003 05:18 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 24-28 November 2003

Additions to Medsafe's Web site from 24-28 November 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/emi/CMIForm.asp>

New - Concerta, Hygroton, Isotane

Updated - Aricept, Epilim, Kemadrin, Maxolon, Resonium-A

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Moclobemide, Cetrotide,

Updated - Anafranil, BeneFix, Bicillin L-A Tubex, Brondecon Elixir, Clane, Climara 50 and Climara 100, Nuvelle, Prinivil, Progynova, Xylocard 100 and Xylocard 500

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/Regulatory/consultants.htm>

This has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 27 November 2003 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

10/05/2004 03:46 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 3-7 May 2004

Additions to Medsafe's Web site from 3-7 May 2004

HOT TOPICS

Alerts/Letters - <http://www.medsafe.govt.nz/hot/RecallMay04.htm>

Information on a consumer recall of contaminated products has been added

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Adenocor, Calcium Resonium, Cordarone X, Danocrine, Epilim oral, Fortral, Plaquenil, Plavix, Primacor, Resonium A

Support Groups - <http://www.medsafe.govt.nz/Consumers/support.htm#Alzheimer's>
The Alzheimers New Zealand contact details have been updated

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Azopt, Min-I-Jet Lignocaine Hydrochloride (CSL)

Updated - Aldara, Adrenaline Hydrochloride Min-I-Jet (CSL), Aspro, Avaxim, Cancidas, Cefazolin, Cialis, Dysport, Herceptin, Innohep, IPOL, Lipex, Marcain Dental with Adrenaline, Seretide Inhaler, Synacthen, Synacthen Depot, Zelmac

Prescriber Update Articles - <http://www.medsafe.govt.nz/Profs/PUarticles/Statinmyop.htm>
An article entitled Myopathy with Statins: Check CK Levels and Interactions has been added

OTHER INFORMATION

Vacancies - <http://www.medsafe.govt.nz/Other/vacancyTLC.htm>
A vacancy for a Team Leader Medicines Control has been added

Becci Slyfield



<http://www.medsafe.govt.nz>



OFFICIAL INFORMATION ACT

05/09/2005 11:02 a.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 29 August-2 September 2005

Additions to Medsafe's Web site from 29 August-2 September 2005

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Femtran, Provera, Provera HD

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Clarac, Stromectol

Updated - Celapram, Dantrium IV, Drolectan, Epikim IV, Epilim (tablets, liquid and syrup), Fluox, Fosamax, Invanz, Iressa, Ismo 20, Lexapro, Relenza, Rifadin, Rifinah, TMP, Vaqta

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 2 September 2005 has been added

GMP Certified Contract Testing Laboratories -

This page has been updated

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.tgamedsafe.org>

There are no updates this week.

Becci Slyfield

<http://www.medsafe.govt.nz>

20/01/2006 06:01 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 9-20 January 2006

Additions to Medsafe's Web site from 9-20 January 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Vaxigrip Junior

Updated - Cialis, Ethyol, Ezetrol, Invirase, Ketalar, Noroxin, Primaxin, Stamaril, Stengen, Vaxigrip

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The outcome of the December 2005 out-of-session consultation with the MCC is now available. The recommendations have been accepted by the Minister's Delegate. Medsafe agrees with these recommendations. It is intended that the changes should be notified in the Gazette on 2 March 2006.

Intention to object to any of these recommendations should be lodged with the MCC secretary no later than 3 February 2006 and should be together with a statement of the safety grounds on which the objection is based. See Dates and Deadlines for the closing date to submit supporting safety data for objections.

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Avastin, Cefazolin injection and Cefazolin Sandoz, Polaramine, Zadine

Updated - Aromasin, Cromolux, Dilantin, Epilim, Ezetrol, Gopten, HBvaxPRO, Isoptin injection, Isoptin and Isoptin SR tablets, Noroxin, Odrik, Pentasa, Primaxin, Prostin VR, Ufexil, Xalacom, Xalatan, Zofran injection, Zofran tablets, Zofran Zydis

Interchangeable Status - <http://www.medsafe.govt.nz/Profs/imm.htm>

List of Interchangeable Multi-Source Medicines has been updated

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 12 and 19 January 2006

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.tgamedsafe.org/>

There has been a change to the information on the home page under 'Introduction to the project'

Becci Slyfield

20/02/2006 05:32 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13-17 February 2006

Additions to Medsafe's Web site from 13-17 February 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Cromolux, Fortovase, MeNZB, Primacor, Stromectol

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - DP-Risperidone

Updated - AliMTA, Elocon, Epilim IV, Fluvax, Fucidin, m-Eslon, MeNZB, Multiload, Rapamune, Reductil, Skincalm, Stromectol, Varivax, Vytorin, Zyprexa IM

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/Regulatory/consultants.htm>

This list has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 9 February 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.jtaproject.com

There are no updates to this site this week

Becci Slyfield

<http://www.medsafe.govt.nz>

[REDACTED]
17/03/2006 04:40 p.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13-17 March 2006

Additions to Medsafe's Web site from 13-17 March 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Epilim IV

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Trileptal oral suspension, Vermox

Updated - Avastin, Biostate, Ipratropium Steri-Neb, Pneumovax 23, Risperdal, Teril, Topamax, Trileptal tablets

List of Interchangeable Multi-source Medicines -

<http://www.medsafe.govt.nz/Profs/imm.htm>

This list has been updated:

New - Lamotrigine

Updated - Doxazosin, Terbinafine

REGULATORY INFORMATION

GMP Certified Contract Testing Laboratories -

<http://www.medsafe.govt.nz/Regulatory/contractTesting.htm>

This list has been updated.

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 16 March 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.tgamedsafe.org

There are no updates to this site this week

Becci Slyfield
[REDACTED]

<http://www.medsafe.govt.nz>
[REDACTED]

07/04/2006 05:23 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 27 March - 7 April 2006

Additions to Medsafe's Web site from 27 March - 7 April 2006

HOT TOPICS

Alerts/Letters - Unapproved prescription and pharmacist-only medicines from China - April 2006

Director-General's Statement Under Section 98 of the Medicines Act 1981 -

<http://www.medsafe.govt.nz/hot/Alerts/ChineseMed/DGStatement.htm>

Photos of Unapproved prescription and pharmacist-only medicines from China -

<http://www.medsafe.govt.nz/hot/Alerts/ChineseMed/Photos.htm>

Consultation - ANZTPA - <http://www.medsafe.govt.nz/hot/TTCconsultation.htm>

A Consultation programme released for the establishment of the Australia New Zealand Therapeutic Products Authority has been added

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Colgout, Covensyl Plus, Premarin, Premia, Nordette, Trifeme, Triphasil, Velcade

Updated - Betaferon, Daktarin, Efexor, Efexor-XR, Epilim oral, Herceptin, Loette, Losec, Minulet, Monofeme, Predonium, Recormon, Trileptal

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The agenda for the 35th meeting of the MCC is now available for consultation. A date for the meeting will be published shortly. Interested bodies have until 19 May to submit comments on agenda items. Please note that the remainder of the 34th agenda will also be considered at this meeting and that the consultation for this meeting has already occurred. -

<http://www.medsafe.govt.nz/Profs/class/agen35.htm>

Dates and Deadlines have also been updated -

<http://www.medsafe.govt.nz/Profs/class/dates.htm>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Paroxetine, Heparinised Saline, Lipiodol, m-Cefazolin, Methotrexate Ebewe

Updated - Avandia, Betaferon, Cafergot, Cefazolin and Cefazolin Sandoz, Cefotaxime, Ceftriaxone, Clorotir, Clozaril, Flameril, Flameril Retard, Miochol-E, Norcuron, Orzel, Ospamox, Penicillin G Sodium, Permax, Recormon, Ritalin and Ritalin SR, Seroquel, Zenapax, Zyprexa

Prescriber Update Articles

Leflunomide and Pneumonitis -

<http://www.medsafe.govt.nz/Profs/PUarticles/LeflunLung.htm>

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 30 March and 6 April 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.jtaproject.com

The following NEW information has been added:

- **Child-resistant packaging requirements for therapeutic goods - consultation**
<http://www.anztpa.org/consult/crp.htm>
- **Second meeting of the Joint Interim Expert Advisory Committee on Standards**
<http://www.anztpa.org/committees/jieacs.htm#second>
- **Second meeting of the pharmacopoeial sub-committee of the Joint Interim Expert Advisory Committee on Standards to consider the default standard for the ANZTPA**
<http://www.anztpa.org/committees/jieacs.htm#ps2>

Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT

14/09/2007 03:41 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 10-14 September 2007

Additions to Medsafe's Web site from 10-14 September 2007

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Tykerb, Voltfast

Updated - Avandia, Cardizem CD, Cellcept, Copaxone, Fosamax Plus, Fuzeon, RotaTeq, Voltaren injection, Voltaren suppositories, Voltaen tablets

Importing Medicines - <http://www.medsafe.govt.nz/Consumers/MIET/ImportMedicines.asp>
A new section on importing medicines has been added

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profis/Datasheet/DSForm.asp>

New - Kenacomb, Tykerb

Updated - Codeine Phosphate, Daclin, Epilim IV, Epilim (tablets, syrup and liquid), Fuzeon, Humira, Rotarix, Saizen, Sporanox capsule, Sporanox oral solution, Tambocor and Tambocor CR, Verpamil and Verpamil SR

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/regulatory/consultants.asp>

This list has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 30 August 2007 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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Becci Slyfield

[Redacted]

To: [Redacted]
cc:
bcc:

21/09/2007 04:38 p.m.

Subject: Additions to Medsafe's Web site from 17-21 September 2007

Additions to Medsafe's Web site from 17-21 September 2007

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Imovane

Updated - Azopt, Cardinol LA, Epilim IV, Epilim Oral, Fortovase, Malarone, Meningitec, Naramig, Trasyolol

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Rectogesic

Updated - Atacand, Cataflam, Codeine Phosphate, Copegus, Infanrix-hexa, Kaletra, Naropin, Pegasys, Pegasys RBV, Seroquel, Sumagran Active, Voltaren Rapid

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 16 August and 20 September 2007 have been added

Medical Devices - <http://www.medsafe.govt.nz/Regulatory/MedicalDevices/condoms.asp>
Requirements for Condoms has been added

Medicines Classification Committee

Agenda for 38th Meeting (December 2007) of the Medicines Classification Committee has been added - <http://www.medsafe.govt.nz/profs/class/agen38.htm>

Dates and Deadlines have been updated - <http://www.medsafe.govt.nz/profs/class/dates.asp>

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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Becci Slyfield

[Redacted]



30/06/2008 11:46 a.m.

To:
cc:
bcc:



Subject: Additions to Medsafe's Web site from 16-27 June 2008

Additions to Medsafe's Web site from 16-27 June 2008

HOT TOPICS

Alerts/Letters

Eltroxin (levothyroxine) - June 2008

Media Release - <http://www.medsafe.govt.nz/hot/media/2008/Eltroxin.asp>

Dear Dr Letter sent by Medsafe - <http://www.medsafe.govt.nz/hot/alerts/Eltroxin.asp>

Dear Dr Letter sent by GlaxoSmithKline (1329kb this is a pdf document and Acrobat Reader is required for viewing) - <http://www.medsafe.govt.nz/hot/alerts/Eltroxin.pdf>

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Dilantin, Dilatrend, Efexor-XR, Humira, Hypnovel, Loette, Minulet, Neotigason, Synflex, Trifeme, Triphasil, Varivax

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Clopidogrel, Bicalox, Fluorescein

Updated - Apo-Doxazosin, Augmentin, Avandia, Baraclude, Bezalip, Cisplatin (Mayne Pharma), Clopixol, Clozaril, DBL Atracurium Besylate, Dostinex, Elidel, Eloxatin, Epilim IV, Epilim tablets, syrup and liquid, EpiPen, EpiPen Junior, Fluanxol, Genox, Haldol, Humira, Maxalt, Minirin, Modavigil, Neotigason, Nizoral, Norspan, OxyContin, OxyNorm capsules and liquid, OxyNorm injection, Precedex, Prezista, Prostin E2, Pulmozyme, Remicade, Seretide Accuhaler, Seretide Inhaler, Tegretol, Trandate, Trizivir, Zelmac, Zevalin, Ziagen solution, Ziagen tablets, Zyban

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 19 June 2008 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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Becci Slyfield

08/05/2009 03:47 p.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 4-8 May 2009

Additions to Medsafe's Web site from 4-8 May 2009

HOT TOPICS

Media Releases - <http://www.medsafe.govt.nz/hot/media/2009/teething.asp>
Update on the use of "teething" gels containing choline salicylate in children - results of Medsafe's review

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Efudix, Fexofast

Updated - Diastop, D-Penamime, Flucazole, Fluconazole, Lithicarb FC, Noflam, Nupentin, Tramedo, Trisul-Tabs

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Kenacomb ointment

Updated - Avomine, Brufen syrup, Brufen tablets, Ceenu, Diastop, D-Penamime, Efudix, Epilim IV, Epilim, Eprex, Florinef, Flucazole, Fluconazole, Hepsera, Hiberix, Humira, Imuran, Jadelle, Kabiven G11, Kabiven G19, Kaletra, Kenacomb, Kivexa, Lithicarb FC, MabThera, Megace, Mersyndol, Mycostatin, Neorecormon, Noflam, Nupentins, Questran Lite, Sabril, Tramedo, Trisul, Trizivir, Vesicare

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 8 May 2009 has been added

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Becci Slyfield
[REDACTED]

<http://www.medsafe.govt.nz>
[REDACTED]

15/05/2009 04:36 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 11-15 May 2009

Additions to Medsafe's Web site from 11-15 May 2009

Reminder: Medsafe is seeking feedback on the consultation document - Proposed Changes to the Fees Payable Under the Medicines Regulations 1984. Feedback is requested by **22 May 2009**

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Adalat OROS, Adalat tablets, Angiomax, Arava, Cardinol, Cerazette, Epilim, Epilim IV, Fosmax, Fosmax Once Weekly, Gliben, Headway, Janumet, Januvia, Nasaclear, OncoTICE, Orgalutran, Ovestin cream, Phenate, Piram-D, Sabril, Triamizide, Vesicare, Zetop

INFORMATION FOR HEALTH PROFESSIONALS

Prescriber Update

May 2009 -

http://www.medsafe.govt.nz/profs/PUArticles/PDF/Prescriber%20Update_May09.pdf

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Tygacil, Zetop

Updated - ACB, Amizide, Aratac, Cardinol, Cardizem CD, Clopress, Crinone, Diurin 40, Dopress, Entrel, Ferrum H, Gliben, Headway, Janumet, Januvia, Logem, Martindale Pharma Acetylcysteine, Micreme vaginal cream, Nasaclear, Norvir, Pacific Bupirone out, Phenate, Piram-D, Prog, Remicade, Skincalm, Tambocor, Triamizide

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 14 May 2009 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

11/06/2010 05:01 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 31 May - 11 June 2010

Additions to Medsafe's Web site from 31 May - 11 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Immucyst BCG, Serophene

Updated - Betaferon, Byetta, Dulcolax, Fosamax, Fosamax, Isentress, Lipex, Tareeva, Velcade, Viramune

Re-published in PDF (no changes to content) - Condyline, Etidrate, Genox, Glucobay, Hypam, Lithicarb FC, Lora-tabs, Metamide, Metoclopramide

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Classification Process - <http://www.medsafe.govt.nz/profs/class/classificationprocess.asp>

This page has been updated

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

This page has been updated

Minutes of the Medicines Classification Committee Meetings -

<http://www.medsafe.govt.nz/profs/class/mccMin13April2010.htm>

Minutes of the forty-third meeting of the Medicines Classification Committee - 13 April 2010, have been added

Prescriber Update Articles - <http://www.medsafe.govt.nz/profs/PUarticles.asp>

The June 2010 edition of Prescriber Update, including the following articles have been added

- Dextropropoxyphene withdrawal on 1 August 2010 - a reminder
- Methylphenidate - updated guidance when treating children
- Cough and cold medicines - update and reminder
- Tramadol - key points for prescribing
- Omeprazole and risk of hypomagnesaemia
- Update on rotavirus vaccines
- Interaction: Sodium valproate and carbapenems - new information
- Case report: Stevens-Johnson syndrome associated with the use of allopurinol
- Codeine - classification and labelling changes
- Adverse reactions associated with intra-articular use of local anaesthetics
- Acitretin (Neotigason) - points to remember
- Warfarin - reports of serious adverse reactions continue
- Zoledronic acid associated with adverse effects on renal function
- Medicine recalls
- Alendronate case report - the importance of patient counselling
- Medicine quality complaints

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Timol, Serophene, Ubistesin forte

Updated - Betaferon, Byetta, Comtan, Fibalip, Fosamax, Immucyst BCG, Imuprine, Isentress, Lipex, Nozinan, Panadol caplets, ReTrieve, Rexacrom, Risperon, Tarceva, Terazosin, Velcade, Vimpat, Xigris, Xylestesin-A

Re-published in PDF (no changes to content) - Aciclovir, Brevinor, Brevinor-1, Condyline, Gentamicin, Glucobay, Lucentis, Noriday, Norinyl-1, Normin, Synphasic

Medical Devices - <http://www.medsafe.govt.nz/profs/device-issues.asp>

Medsafe Statement - Graseby MS-Series Syringe Drivers - Further Extension of Deadline

Regulatory Issues - <http://www.medsafe.govt.nz/profs/Rlss/restrict.asp>

The restrictions on the supply of Clozapine have been updated

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 3 June 2010 has been added

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Becci Slyfield

<http://www.medsafe.govt.nz>

18/06/2010 05:09 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 14-18 June 2010

Additions to Medsafe's Web site from 14-18 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Imuprine, ReTrieve,

Updated - Avastin, Camptosar, Januvia, Konakion MM, Loxamine, Madopar

Re-published in PDF (no changes to content) - Adacel, Adacel Polio, Asamax, Asamax 500, Avaxim, Disipal, Dukoral, IPOL, Lemnis Fatty Cream HC, Liposort, Locoid, Locoid C, Menomune ACYW-135, Mildison, Noriday, Norinyl-1 21 day, Norinyl-1 28 day, Pimafucort, Quadracel, Stamaril, Typhim vi, Vivaxim

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

Updated - Avastin, Baraclude, Camptosar, Cefalexin, Epilim and Epilim EC, Epilim intravenous, Fosamax, Genotropin, Gutron, Januvia, Konakion MM, Largactil, Loxamine, Madopar, Spiriva, Zoloft,

Re-published in PDF (no changes to content) - Adacel, Adacel Polio, Advate, Aerrane, Amyl Nitrite, Asacol, Asamax 500 suppository, Asamax 500 tablet, Avaxim, Cal D Forte, Cernevit, Codeine Phosphate, Curam injection, Curam tablet and suspension, Dexamphetamine sulphate, Disipal, Dukoral, Ephedrine Hydrochloride, Extraneal, Feiba NF, Fleet Phospho-Soda, IPOL, Isoniazid, Lemnis Fatty Cream HC, Lipocort, Locoid, Locoid C, Menomune ACYW-135, Methatabs, Midazolam, Mildison Lipocream, Pethidine, Phenobarbitone BP, Pimafucort, Quadracel, Sodium Chloride, Stamaril, Terbinafine-DP, Thalidomide, Typhim Vi, Vivaxim, Voluven

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 17 June 2010 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

25/06/2010 10:35 a.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 21-25 June 2010

Additions to Medsafe's Web site from 21-25 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Avomine, Brolene, Cefalexin Sandoz, Dimetriose, Durogesic, Leunase, Mersyndol, Soframycin, Telnase, Vallergan and Vallergan Forte

Updated - Batrafen nail lacquer, Hepsera, Rifadin

Re-published in PDF (no changes to content) - Adenocor, Anthisan, Apidra and Apidra SoloStar, Arava, Batrafen cream and solution, Calcium Resonium, Copaxone, Cordarone X, Daonil, Epilim, Fasturtec, Flagyl, Frisium, Ikorel, ImmuCyst, Imovane, Methoblastin, Myocrisin, Neulactil, Noflam, Norpress, Nupentin, Omezol, Plaquenil, Plavix, Primacor, Proctosedyl, Resonium-A, Sculptra, Sofradex, Solian, Stemetil, Surgam, Telfast

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - DP-Quetiapine, Provive MCT-LCT, Sudomyl, Vidaza

Updated - Bridion, Hepsera, Tisseel

Re-published in PDF (no changes to content) - Adenocor, Anthisan, Apidra and Apidra SoloStar, Arava, Avomine, Batrafen cream and solution, Batrafen nail lacquer, BeneFIX, Brolene, Calcium Resonium, Chloromycetin, Copaxone, Cordarone X, Daonil, Dimetriose, Durogesic, Elidel, Epilim, Estraderm, Exelon, Exelon patch, Fasturtec, Flagyl and Flagyl-S, Frisium, Gastrolyte, Holoxan, Ikorel, ImmuCyst, Imovane, Leunase, Loette, Meningitec, Mersyndol and Mersyndol Forte, Metronidazole, Monofeme, Myocrisin, NeisVac-C, Neulactil, Oliclinomel, Onkotrone, Paradex, Plaquenil, Plavix, Prevenar, Primacor, Proctosedyl, Recombinate, Resonium-A, Rifadin, Sabril, Sculptra, Sevoflurane, Sofradex, Soframycin, Solian, Stemetil, Suprane, Surgam, Tazocin EF, Telfast, Telnase, Uromitexan, Vallergan Forte, Xyntha

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Becci Slyfield

27/09/2010 04:26 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 20-24 September 2010

Additions to Medsafe's Web site from 20-24 September 2010

HOT TOPICS

Media Releases -

<http://www.medsafe.govt.nz/hot/media/2010/Recall6ProductsSep10.asp>

Medsafe recalls six products with undeclared prescription medicines

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Aristocort, Ativan, Atropt, Calcium Folate Ebewe, Capoten, Carboplatin Ebewe, Chlorafast, Cilicaine, Cilicaine VK, Cisplatin Ebewe, Coumadin, Diamox, Diamox, Docetaxel Ebewe, Doxorubicin Ebewe, Epirubicin Ebewe, Eutroxsig, Ferrosig, Florinef, Fludarabine Ebewe, Fungilin, Gemcitabine Ebewe injection concentrate, Gemcitabine Ebewe powder for injection, Irinotecan Ebewe, Kenacort A10, Kenacort A40, Lycinate, Megace, Methotrexate Ebewe, Myambutol, Nilstat, Nilstat, Normison, Oxaliplatin Ebewe, Pravachol, Pro-banthine, Q200 and Q300, Questran Lite, Robinul, Serenace injection solution, Serenace tablet and liquid, Urex Forte, Vinorelbine Ebewe

Updated - BeneFIX, Ciproxin IV, Ciproxin tablet, Daclin, Diflucan One capsule, Duac, Fluorouracil Ebewe, Fragmin, Hiberix, Kenacomb, Mitozantrone Ebewe, Paclitaxel Ebewe, Parnate, Pexsig, Sprycel, Sutent, Ventavis

Re-published in PDF (no changes to content) - 2% Xylocaine Dental with Adrenaline, 3% Citanest Dental with Octapressin, Agenerase capsules, Agenerase oral solution, Beclazone CFC-Free inhaler, Cardizem, Clomazol, Eloxatin, Epilim tablet and oral liquid, Ipratropium Steri-Nebs, Levothyroxine, M-Cefazolin, Noflam, Nupentin, Oraquix, Pacifen, Pacific Buspirone, Paxam, Pindol, Piram-D, Quetapel, Ridaura, Rifadin, Risperon, Sabril, Salamol CFC-Free, Somac, Sotalol, Stelazine, Stieprox, Sumagran Active, Tramedo, Trisul, Vancomycin, Ventolin inhaler aerosol metered, Verpamil, Xergic, Zovirax cold sore cream

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Risperidone

Updated - Aclasta, BeneFIX, Cilazapril-AFT, Daclin, DBL Phenytoin injection BP, Diflucan One capsule, Engerix B, Estrofem, Fragmin, Infanrix-Hexa, Infanrix-IPV, Kliogest, Klioavance, MabCampath, Mencevax ACWY, NovoRapid, OxyContin, OxyNorm, Parnate, Prostin, Pregon, Simponi, Sutent, Trisequens, Typherix, Vagifem, Voltaren D, Voltaren injection, Voltaren SR, Voltaren suppositories, Voltaren tablets, Voltfast

Re-published in PDF (no changes to content) - 2% Xylocaine Dental with Adrenaline, 3% Citanest Dental with Octapressin, Aratac, Calcium Folate, Carboplatin Ebewe, Cardizem, Cisplatin Ebewe, Docetaxel Ebewe, Doxorubicin

Ebewe, Eloxatin, Epirubicin Ebewe, Floxapen, Fluorouracil Ebewe Fludarabine
Ebewe, Gemcitabine Ebewe, Kivexa, Loxalate, MabCampath, Methotrexate Ebewe,
Mitozantrone Ebewe, Neo-Cytamen, Oraqix, Oxaliplatin Ebewe, Stelazine,
Suboxone, Temgesic, Trizivir, Ultravist, Urografin, Vergo 16, Vinorelbine Ebewe,
Ziagen solution, Ziagen tablet, Zofran Zydis

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 16 and 23 September 2010 have been added

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Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE OFFICIAL INFORMATION ACT

18/01/2011 04:12 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13 December 2010 - 14 January 2011

Additions to Medsafe's Web site from 13 December 2010 - 14 January 2011

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Carbaccord, Compound Sodium Lactate (Hartmann's), DP-Omeprazole, Epiccord, Estradot, Irinoccord, Ondanaccord, Oxaliccord

Updated - Comtan, Cozaar, Renitec and Renitec M, Permax, Apidra and Apidra Solostar, Dopergin, Xarelto, Luveris, Betoptic S, Pentasa, Camptosar, Volibris, Lithicarb FC, Avaxim, Januvia, Janumet, Comvax, Lantus, Cubicin

Re-published in PDF (no changes to content) - Humalog cartridge and Humalog Mix, Humalog vial, Humulin cartridge, Humulin vial

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

Minutes of the November 2010 Medicines Classification Committee Meeting -

<http://www.medsafe.govt.nz/profs/class/mccMin2Nov2010.htm>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Arrow Rocuronium, Carbaccord, Cefazolin-AFT, Compound Sodium Lactate (Hartmann's), DP-Omeprazole, Epiccord, Eyeprost, Irinoccord, Mestane, Mucinex, Mylan, Noradrenaline, Ondanaccord, Oxaliccord, Ropivacaine-AFT, Silvasta, Solox Relief, Univent

Updated - Apo-Allopurinol, Camptosar, Catapres TTS, Cernevit, Comvax, Coumadin, Cozaar, Diclofenac Sandoz, Epilim, Estradot, Fasturtec, Feiba NF, Gastrolyte, Humira, Hysite, Ibuprofen (Ethics), Jadelle, Janumet, Januvia, Leunase, Luveris, Modecate and Modecate Concentrate, Neulastim, Neupogen, Omnipaque, Permax, Plavix, Premarin, Renitec and Renitec M, Sabril, Sevoflurane, Synermox, Tamoxifen Sandoz, Taxol, Tracrium, Volibris

Re-published in PDF (no changes to content) - 3TC oral solution, Arrow Bendrofluzaide, Arrow Tramadol, DBL Doxorubicin Hydrochloride, Pneumo 23, Tubersol

REGULATORY INFORMATION

Certified Clinical Trial Sites - <http://www.medsafe.govt.nz/regulatory/CSSites.htm>

These have been added

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 9 December 2010, 23 December 2010 and 13 January 2011 have been added

Guidelines and Codes

Guideline on the Regulation of Therapeutic Products in New Zealand
Part 11: Good Clinical Research Practice and obtaining approval for clinical trials
and new reformatted forms have been added -
<http://www.medsafe.govt.nz/regulatory/guidelines.asp#Part11>

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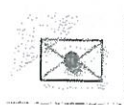
Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT



11/08/2011 03:00 p.m.

To:
cc:
bcc:



Subject: Additions to Medsafe's Web site from 27 June - 5 August 2011

Additions to Medsafe's Web site from 27 June - 5 August 2011

HOT TOPICS

Australia New Zealand Therapeutic Products Agency (ANZTPA)

Fact Sheet, dated 28 June 2011 - <http://www.medsafe.govt.nz/hot/anztpa.asp>

New Amendments to the Medicines Regulations 1984 -

<http://www.medsafe.govt.nz/hot/NewAmendmentstoMedicineRegs.asp>

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Candestar, Cholvastin, Dapsone, Daunorubicin, Femoston 2/10, Miostat intraocular, Ozole, Paracetamol + Codeine, PicoPrep, Prepkat-C, Vaclovir, ZolaCos CP

Updated - Arrow - Sumatriptan, Arrow - Venlafaxine XR, Avastin, Avigra, Botox®, Ciproxin, Cleviprex, Clozaril, Colofac, Cordarone X, Cymevene, EpiPen, EpiPen Jr, Eprex, Florinef, Fluarix, Fludara, Fludara oral, Fluox, Fragmin, Fucithalamic, Gardasil, Heparin Sodium (Pfizer), Homedin, Iressa, Isopto Carpine, Kogenate FS, Kuvan, Losec, Luvox, Lyrica, Maxalt, Maxalt Melt, Maxidex, Metopirone, MyGran, Novatrelin, Ozole, Pentasa, Ponstan, Sandomigran, Serc, Silagra, Stieprox, Symmetrel, Synflorix, Temaccord, Vesicare, Vimovo, Xanax, Zanidip, ZolaCos CP, Zolof

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - AFT-Pamidronate, Ciclopirox, Co-Plavix, Desmopressin-PH&T, DisCoVisc, Duovisc, Glycoprep powder, Glycoprep-C, Hydrocortisone Butyrate Cream, Irinotecan Actavis 100, Irinotecan Actavis 40, Locacorten-Viaform, Loniten, Octalbin, Olanzapine Orodispersible tablet, Olanzapine tablet, Ondansetron-Clarix, Panvax vaccine, Provisc, Sulphacetamide Sodium Eye Drops, Terbinafine (Dr Reddy's, Travatan Z, Vigamox

Updated - Actilyse, Andriol Testocaps, Androderm, Anzatax, Aricept, Arrow - Metformin 1000, Arrow - Metformin 250, Arrow - Metformin 500, Arrow - Metformin 850, Avastin, BCG vaccine (freezedried), Biodone Forte, Botox®, Bridion, Candestar, Ceftriaxone-AFT, Cefuroxime-AFT, Cholvastin, Cisplatin Ebewe, Cleviprex, Clozaril, Colofac, Copegus, Cordarone X, Cosudex, Coversyl Plus, Cymevene, Cytarabine, Dapsone, Daunorubicin, DBL® Acetylcysteine, DBL® Atracurium Besylate Injection, DBL® Calcium Gluconate, DBL® Cefotaxime Sodium for Injection, DBL® Cefoxitin Sodium, DBL™ Epirubicin Hydrochloride, Eligard 1 Month, Eligard 3 Month, Eligard 4 Month, Eligard 6 Month, Engerix-B, Engerix-B vaccine, Epilim Intravenous, Epilim Liquid, EpiPen, Eumovate, Femoston 2/10, Florinef, Fluarix, Fludara, Fludara oral, Fludarabine Actavis 50, Fluox, Fragmin, Fucithalamic, Fuzeon, Gardasil, Gemcitabine Actavis 1000, Havrix 1440 vaccine,

Hepatitis B Immunoglobulin-VF 100IU, Hepatyrrix, Hiberix, Humira, Imovane, Infanrix-hexa, Infanrix-IPV, Isopto Carpine, Kogenate FS, Kuvan, Lithicarb FC, Logem, Lucrin, Lucrin Depot Luvox, Lyrica, Maxidex, Mencevax ACWY vaccine, Mersyndol, Metformin, Metopirone, Miostat intraocular, MyGran, Normal Immunoglobulin-VF, Novatretin, Omezol, Orenzia, Ozole, Paclitaxel Actavis, Paracetamol + Codeine, Pegasys, Pegasys RBV, PicoPrep, Pradaxa, Predonium, Predonium DS, Premarin, Premia 2.5 Continuous, Prepkat-C, Prezista, Priorix, Rocuronium, Rotarix, Sandomigran, Serc, Silagra, Simulect, Stieprox Liquid, Sutent, Symmetrel, Synflorix, Tamsulosin-Rex, Tazocin, Temaccord, Tetanus Immunoglobulin-BF, Topamax, Twinrix, Twinrix Junior, Tygacil, Typherix, Ursofalk, Varilrix, Vesicare, Xanax, Your pharmacy Paracetamol Plus, Zanidip, ZolaCos CP, Zoladex, Zoloff, Zoster Immunoglobulin-VF

Regulatory Issues

Sativex Oromucosal Spray - Requirements for Prescribers

<http://www.medsafe.govt.nz/profs/Rlss/Sativex.asp>

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 30 June, 7 July, 14 July, 21 July, 28 July, and 4 August have been added

Guidelines and Codes

Guideline on the Regulation of Therapeutic Products in New Zealand - Part 5:

Labelling of medicines and related products - Edition 1.0 August 2011 -

<http://www.medsafe.govt.nz/regulatory/guidelines.asp#Part 5>

Label Statements Database - <http://www.medsafe.govt.nz/regulatory/labelling.asp>

The Label Statements Database has been updated to include Australian label statements for paracetamol and aspirin and make it clear that these are an acceptable alternative. The Australian wording for aspirin will become the mandatory form of wording in September 2012. This follows from the intention reported in the minutes of the 45th meeting of the Medicines Classification Committee held in April 2011.

The requirement for labels to include the warning that paracetamol should not be used in children under 2 years old has been removed. This warning is not required in Australia.

The statements that ibuprofen solid dose forms sold as general sale medicines should not be used in children under 6 years old or in adults over 65 years old, without doctor's advice, have been added. These were omitted in error from Edition 1 of the database, and are re-instated in this update.

The database has also been amended to clarify that the warning statements required for loperamide apply only to packs sold as general sale medicines.

The warning against using cough and cold medicines with other medicines intended to treat symptoms of the common cold has been modified to indicate that such use may be acceptable on a doctor's or pharmacist's advice.

Permitted Colourings for use in Medicines -

<http://www.medsafe.govt.nz/regulatory/Guideline/PermittedColourings.asp>

Schedule A - Declaration to accompany Consumer Medicine Information (CMI) submitted for Publication -

<http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/ScheduleAForm10.5.doc>

This form has been updated to remove the option for pdf replacement of html CMI. Only "new" or "revised" options remain.

Medical Devices / WAND -

<http://www.medsafe.govt.nz/regulatory/DevicesNew/Devices.asp>

The medical devices pages of the Medsafe website have been revised to provide information on a wide range of topics. These topics include; understanding the definition of a medical device, how to conduct basic WAND tasks, advertising of medical devices, clinical trials, in-vitro diagnostic (IVD) devices, and how to conduct a recall or corrective action. Sponsors are encouraged to use this revised information as their first point of call when they have questions about medical devices

This e-mail has been sent to you from Medsafe - a business unit of the Ministry of Health. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority.

If you no longer wish to receive these emails, please send an email to becci_slyfield@moh.govt.nz with unsubscribe in the subject line.

Becci Slyfield

<http://www.medsafe.govt.nz>



UNCLASSIFIED INFORMATION ACT



14/11/2011 06:13 p.m.

To:
cc:
bcc:



Subject: Additions to Medsafe's Web site from 8 September - 14 November 2011

Additions to Medsafe's Web site from 8 September - 14 November 2011

HOT TOPICS

Media Releases

The following media releases have been issued

26 Oct 2011 - Worldwide withdrawal of Xigris (drotrecogin alfa) -

<http://www.medsafe.govt.nz/hot/media/2011/WorldwidewithdrawalofXigris.asp>

6 Oct 2011 - Medsafe recalls two products with undeclared prescription medicines -

<http://www.medsafe.govt.nz/hot/media/2011/UndeclaredPrescriptionMedicinesOct2011.asp>

30 Sept 2011 - Medsafe Warns of Dangers of Purchasing Medicines Online -

<http://www.medsafe.govt.nz/hot/media/2011/DangersOfPurchasingMedicinesOnline.asp>

15 Sept 2011 - Pradaxa (dabigatran etexilate): Questions and Answers (updated 31 October 2011) -

<http://www.medsafe.govt.nz/hot/media/2011/DabigatranQandA.asp>

INFORMATION FOR CONSUMERS

Consumer Medicine Information

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Propecia

Quality and Safety of Medicines

Vaccine Safety -

<http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp>

This page has been added

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The following pages have been updated

Agenda for the 46th Meeting of the Medicines Classification Committee

Meeting - <http://www.medsafe.govt.nz/profs/class/agen46.htm>

Classification Process -

<http://www.medsafe.govt.nz/profs/class/classificationprocess.asp>

Current Amendment to the Classification Schedule -

<http://www.medsafe.govt.nz/profs/class/amendment.asp>

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

Recent NZ Gazette Notices Relating to Classification -

<http://www.medsafe.govt.nz/profs/class/recent.asp>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Actonel, Adenoscan, Adin Nasal Spray, Adin Tablets, Adrenaline, Aldactone, Alendronate Pfizer, Amaryl, Anaccord, Anapen, Angiomax, Apo-Alendronate, Apo-Anastrozole, Apo-Cilazapril, Apo-Cilazapril/HCTZ, Apo-Ciprofloxacin, Apo-Citalopram, Apo-Clarithromycin, Apo-Escitalopram, Apo-Gabapentin capsules, Apo-Gabapentin tablets, Apo-Imiquimod, Apo-Latanoprost, Apo-Leflunomide, Apo-Levetiracetam, Apo-Lisinopril, Apo-Olanzapine, Apo-Pantoprazole, Apo-Sildenafil, Apo-Sildenafil, Apo-Simvastatin, Apo-Topiramate, Arrow-Amlo, Arrow-Amlodipine, Arrow-Carvedilol, Arrow-Cilazapril, Arrow-Combipramol, Arrow-Gabapentin, Arrow-Ipratropium, Arrow-Isotretinoin, Arrow-Paroxetine, Arrow-Quinapril, Arrow-Ranitidine, Arrow-Ropinirole, Arrow-Salbutamol, Arrow-Simvastatin, Arrow-Stavudine, Arrow-Timolol, Atehexal, Atripla, Atorvastatin, Auro-Alendronate, Auro-Cefazolin Pfizer, Auro-Ceftriaxone, Auro-Ondansetron, Auro-Quetiapine, Ava 30, Ava 30 ED, Avage, Avodart, Blephamide, Bonviva, Bosvate, Brufen, Canesten Plus, Captohexal, Cardizem, Cefazolin Pfizer, Ceftriaxone Pfizer, Cefuroxime, Ciclofast, Ciclopoli, Clindamycin ABM, Clopidex, Clopidogrel Sandoz, Clopidogrel Winthrop, Co-Diovan, Cytraccord, Dantrium IV, DBL Zinc Chloride, DermAid, Diltahexal, Diovan, Emend IV, Enidin, Escitalopram, Finaccord, Flagyl, Fluohexal, Frusehexal, Fugerel, Galvus Met, Gammanorm, Genotropin Miniquick, Gilenya, Glimaccord, Glypressin, Humalog, Ibuprofen, Idarubicin Ebewe, Imipenem+Cilastatin RBX, Implanon NXT, Inspira, Intal Forte, Iressa, Javior, Jurnista, Juvederm Ultra XC, Juvederm Voluma XC, Kapanol, Ketek, Lamivudine Alphapharm, Letrozole Sandoz, Lopresor, Losartan HCTad, Losiva, Lumigan RC, Luveris, Lyrinel XL, m-Pergolide, Medrol, Menitorix, Menopur, Merieux, Metformin, Midaccord, Minirin Melt, Mircera, MMF-Panacea Biotech, Motetis, MST Continus, MST Mono, Mucinex, Myfortic, Nexium, Next Choice, Nifehexal, Nodia, NovoMix, Octanate, Octaplas, Olanzaccord, Ondansetron, Ondansetron, Ophthetic, Oralair, Oralcon 30, Oralcon 30 ED, Orudis SR, Oxaliplatin Actavis, Ozurdex, Panadeine, Panadeine Extra, Panafen Plus, Pantoprazole Sandoz, Panvax H1N1, Paracode Extra, Pariet, Phenytoin Sandoz, Picosalax, Poliacel, Probitor, Prolia, Promethazine Winthrop, Pronativ, Propofol, Quetiapine, Ranbaxy-Gabapentin, Ranihexal, Ranibexal, Rasilez, Relestat, Revasc, Rhesonativ, Riamet Dispersible Tablet, Riamet Tablet, Rupatal, Saizen 1.33, Saizen 8, Sildenafil Pfizer, Soliris, Somac, Sotahexal, Stelara, Tassigna, Tatig, Tisseel Fibrin Sealant VH S/D, Triasyn, Tripacel, Tritace, Truvada, Ursosan, Visacor, Vivera, Voltaren Osteo, Wilate, Xalaplus, Xalatan, Zantac tablet, Zarator, Zemaira, Zidoval, Zithromax, Zorac cream, Zorac gel, Zytram XL,

Updated - Abilify, Abraxane, Aclasta, Actrapid, Acular, Alendronate Pfizer, Amisulpride, Arabloc, Aranesp, Arava, Arrow-Cilazapril, Arrow-Citalopram, Arrow-Citalopram, Arrow-Ornidazole, Arrow-Quetiapine, Arrow-Rocuronium, Arrow-Simva, Arrow-Terbinafine, Arrow-Timolol, Auro-Ceftriaxone Pfizer, Avamys, Avodart, Botox, Butacort, Candestar, Cefazolin-AFT, Ceftriaxone Pfizer, Celebrex, Celepram, Celsentri, Certican, Champix, Children's Tixylix Night, Circadin, Citalopram, Cosmegen, Cozaar, Curam Duo, DBL Ephedrine Sulfate, DBL Leucovorin Calcium, DBL Piperacillin And Tazobactam, DBL Sodium Thiosulfate, DBL Vancomycin Hydrochloride, DBL Vinblastine Sulfate, Deca-Durabolin Orgaject, DHC Continus, Diflucan, Donezil, Donezil, Dotarem, Ecotrin, Efexor XR, Eltroxin, Enablex, Ephedrine Hydrochloride, Epilim CR, Erbitux, Estraderm, Eulexin, Exforge, Exjade, Extraneal, Famvir, Feiba NF, Flixotide, Fluanxol Depot, Fluarix, Fresofol, Frumil, Galvus, Glivec, Glivec, Gonal-F, Hepsera, Hysite, Ibiamox, Implanon NXT, Imukin, Imuprine, Integrilin, Iopidine, Isotrex, Kaletra, Kogenate FS, Lamictal,

Lamisil, Lanzol Relief, Largactil, Lasix, Leflunomide Sandoz, Leflunomide Winthrop, Lescol, Levemir, Lopresor, Loxamine, Lucentis, Lucentis, Mabthera, Mabthera, Marcain ± Adrenaline, Marcain Spinal, Mixtard, Mucinex, Multihance, Mylan Fentanyl, Neulactil, Nitroderm, Nitrolingual Aqueous, Noctamid, Norvapine, Norvir, Novoseven RT, Nozinan, Nurofen Migraine 400 Double Strength, Nurofen Migraine 400 Double Strength, Nyogel, Omezol Relief, Onbrez , Onsenal, Oruvail SR, Ovestin Cream, Ovestin Ovula Pessary, Ovestin Pessary, Ovestin Tablet, Oxynorm, Panzytrat, Penmix, Pentasa, Pepzan, Pergoveris, Persantin PL, Pharmacist's Own Pain Relief, Pharmacist's Own Pain Relief Plus, Pharmorubicin, Physioneal 40, Piportil Depot, Pizaccord, Ponstan, Postinor-1, Premia Low, Primacor, Priorix Tetra, Propecia, Protaphane, Quinapril, RA-Morph, Ranbaxy-Cefaclor, Rectogesic, Renagel, Respigen, Revlimid, Saizen 3, Saizen 8, Seroquel, Seroquel XR, Simstatin, Stelara, Stemetil, Stromectol, Sudomyl, Sustanon, Synagis, Synflorix, Synthroid, Tambacor, Tamoxifen Sandoz, Targin, Taxotere, Taxotere, Tegretol, Temaccord, Tilade, Tisseel Fibrin Sealant VH S/D, Stalevo, Tobi, Tykerb, Vergo 16, Vermox Oral Suspension, Vermox Tablet, Vidaza, Viread, Voltaren Rapid, Xalacom, Xylocaine ± Adrenaline, Zantac, Zantac Syrup, Zarontin, Zeldox IM, Zofran Injection, Zofran Tablets, Zofran Zydis, Zytram BD

Re-published in PDF (no changes to content) - Acihexal, Acupan, Advantan, Aldara, Aromasin, Arrow-Gliclazide, Arrow-Tramadol, Benpen, Calcium Disodium Versenate, Cytarabine, Daivobet, Doloproct, Duromine, Durotram XR, Enbrel, Fluorouracil Pfizer, Fucidin, Infanrix, Infanrix Hib, Infanrix IPV-Hib, Infanrix-penta, Intanza, Macugen, Meningitec, Norflex, Nuelin, Nuelin-SR, Ocuflox, One Alpha, Paediacel, Prevenar, Prevenar 13, Rapamune, Reminyl, Skinoren, Solox, Stesolid Rectal Tubes, Streptase, Tambocor, Tramal, Ultraproct, Vaxigrip Junior

M² Medicines Monitoring

<http://www.medsafe.govt.nz/profs/M2MedicinesMonitoring.asp>

This page has been updated

Regulatory Issues

Restrictions on the Prescribing, Supply and Administration of Medicines under the Medicines Act 1981 & the Misuse of Drugs Regulations 1977 -

<http://www.medsafe.govt.nz/profs/RIss/restrict.asp>

This page has been updated

REGULATORY INFORMATION

Forms - <http://www.medsafe.govt.nz/regulatory/forms.asp>

- The following forms have been updated
- CMN Form A
- CMN Form B
- Labelling Declaration Form
- NMA Form
- Proprietary Ingredient Form

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 11 August, 18 August, 25 August, 1 September, 8 September have been added

Guidelines & Codes

Guideline on the Regulation of Therapeutic Products in New Zealand -

<http://www.medsafe.govt.nz/regulatory/guidelines.asp>

Part 5: Labelling of medicines and related product

Update to the Label Statements Database - Edition 1.4, October 2011

Pseudoephedrine has been removed from the listing in the group Cough and cold medicines, as it is now a scheduled prescription medicine and no longer available for use in OTC cough and cold medicines.

Phenylephrine has been added to the group Cough and cold medicines, as companies are re-formulating their products to use this in place of pseudoephedrine.

The warning statement required for topical products, including corticosteroids for topical use, has been revised to "Caution: Contains [names of any preservatives or allergens]" , as the warning applies only if the product contains preservatives or allergens.

The condition for requiring the warning statements for Salicylates has been changed to say "Salicylates, other than aspirin, for oral use". Aspirin has its own set of required warning statements.

The statement "Consult a doctor before use if you are at risk of bleeding problems." was incorrectly included for proton pump inhibitors and has been removed.'

Part 7: Advertising of therapeutic products

This has been added

Part 10: Requirements for information for prescribers and consumers

To include updates relating to changes in the Medicines Regulations

New Zealand Regulatory Guidelines for Medicines

Volume 1: Guidance notes for applicants for consent to distribute new and changed medicines and related products

Part C - Addition of requirements for priority assessment status, minor editorial changes. Remove section on classification and redirect to "Classification" section of website

Parts E, F and G - Deleted as refers to superseded processes

Guideline -

<http://www.medsafe.govt.nz/regulatory/Guideline/NZRGM%20Volume%201.asp>

Summary of Changes -

<http://www.medsafe.govt.nz/regulatory/Guideline/summaryofchanges.asp>

Medicines Assessment Advisory Committee -

<http://www.medsafe.govt.nz/regulatory/MAACcontents.asp>

These pages have been updated

Product/Application Search

Evaluation Timeframes -

<http://www.medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp>

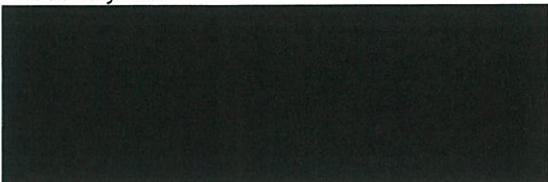
This page has been updated

Weight Management/Weight Loss Products -

<http://www.medsafe.govt.nz/regulatory/Weight/weightcontents.asp>

This page has been updated

Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT

25/02/2013 04:43 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 4-22 February 2013

Additions to Medsafe's Web site from 4-22 February 2013

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Arrow-Quinapril tablet, Stieprox liquid shampoo

Updated - Androderm patch, Anten capsule, Arrow-Amitriptyline tablet, Arrow-Diazepam tablet, Betaloc CR tablet, Betoptic eye drops, Betoptic S eye drops, Bezalip and Bezalip Retard tablet, Bridion solution for injection, Cetrotide powder for injection, Cialis tablet, Cordarone X tablet and injection solution, Disipal tablet, Ebixa tablet lactose free, Ebixa tablet with lactose, Epilim EC and Liquid and 100 Crushable and tablet, Epilim intravenous injection, Humalog solution for injection, Humalog solution for injection cartridge and Humalog MIX25 and MIX50 suspension for injection, Humalog solution for injection pre-filled pen and Humalog MIX25 and MIX50 pre-filled pen, Humulin solution for injection cartridge, Humulin solution for injection vial, Imukin injection solution, Mabthera infusion concentrate, Mencevax ACWY vaccine, Olanzine + Olanzine-D tablet, Pacifen tablet, Premarin tablet, Propecia tablet, Proscar tablet, Quetapel tablet, Risperon oral solution, Rizamelt Orodispersible tablet, Simdax injection, Simponi solution for injection and SmartJect, Staphlex capsule, Sublimaze solution for injection, Tarceva tablet, Tasmart tablet, TMR tablet, Tykerb tablet, Ventavis solution for inhalation, Wartec cream, Zoladex 10.8 implant, Zoladex 3.6 implant

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Agenda for the 40th Meeting of the Medicines Classification Committee meeting has been added - <http://www.medsafe.govt.nz/profs/class/agen49.htm>

Dates and Deadlines page has been updated -

<http://www.medsafe.govt.nz/profs/class/dates.asp>

Gazette Notice for 7 February 2013 relating to classification has been added -

<http://www.medsafe.govt.nz/profs/class/recent.asp>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Alcaine eye drops, Eylea injection solution, Isopto Carpine eye drops, Methotrexate Sandoz injection with diluent, Polyvisc eye ointment, Tobrex eye drops, Victrelis Pegatron Combination Therapy

Updated - Alimta vial, Amirol tablet, Amitrip tablet, Androderm patch, Anten capsule, Apo-Moclobemide FCT, Apo-Terbinafine tablet, Arrow Amitriptyline tablet, Arrow-Diazepam tablet, Aurorix tablet, Avigra tablet, Betnovate lotion, Betnovate-C cream and ointment, Betoptic eye drops solution and Betoptic S eye drops suspension, Bricanyl turbuhaler, Bridion solution for injection, Budenocort powder for inhalation, Cancidas powder for injection, Carafate tablet, CeeNU capsule, Cetrotide powder for injection, Cisplatin ABM injection solution, Clozaril tablet, Codeine

Phosphate tablet, Diane-35 ED tablet, Disipal tablet, Dopress capsule, Droleptan solution for injection, Dynastat powder for injection, Ebixa tablet lactose free, Ebixa tablet with lactose, Elaprase infusion, Eumovate topical cream, Fentanyl solution for injection, Haldol and Haldol Concentrate injection, Humalog solution for injection, Humalog solution for injection cartridge/KwikPen and solution for injection and Humalog MIX25 and MIX50 suspension and pen suspension for injection, Humulin solution for injection cartridge and vial, Hypam tablet, Invanz powder for injection, Largactil tablet and injection and solution, Leflunomide Sandoz tablet, Lucrin solution for injection, Lucrin suspension for injection, Ludiomil tablet, Luvox tablet, Mabthera infusion concentrate, Magnevist solution for injection, Maxolon tablet, Mencevax ACWY vaccine, Muphoran injection solution, Naropin with Fentanyl infusion solution, Neulactil tablet, Nitrados tablet, Norpress tablet, Nozinar tablet and injection and solution, Olanzine + Olanzine-D tablet, Oxytrol patch, Pacifen tablet, Piportil depot injection solution, Premarin tablet, Propecia tablet, Proscar tablet, Quetapel tablet, Risperdal Consta powder for injection, Risperdal tablet and oral solution and orodispersible tablet, Rizamelt orodispersible tablet, Singulair tablet, Solian table and oral solution, Sporanox capsule, Sporanox solution, Staphlex capsule, Stelazine tablet and liquid oral and spansules, Sublimaze solution for injection, Tacrolimus Sandoz, Tamiflu capsule, Tarceva tablet, Tasmart tablet, Tegretol tablet and CR and syrup, Terbinafine-DRLA tablet, TMP tablet, Tofranil tablet, Tykerb tablet, Vimovo tablet, Zarzio solution for injection

Medicines Monitoring

Outcomes of Medicines Previously on M²

<http://www.medsafe.govt.nz/profs/M2MedicinesMonitoringOutcomes.asp>

The following have been added

- Lithium and Diabetes Mellitus Type 2
- Proton Pump Inhibitors and Hypocalcaemia

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 7, 14 and 21 February 2013 have been added

Guidelines & Codes -

<http://www.medsafe.govt.nz/regulatory/Guideline/PolicyForChangingRegistrationSituation.asp>

Medsafe's policy for Changing Registration Situation has been added -

Introductory Regulatory Guidance -

<http://www.medsafe.govt.nz/regulatory/RegulatoryGuidance/Introduction.asp>

This new section has been added

Product/Application Search -

<http://www.medsafe.govt.nz/regulatory/Performance2012.asp>

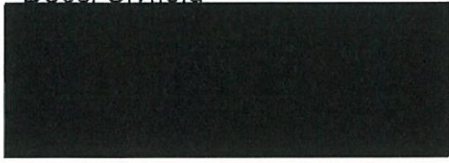
Performance against evaluation timeframes 2012 has been added

This e-mail has been sent to you from Medsafe - a business unit of the Ministry of Health. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority.

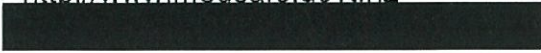
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Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT



06/05/2014 05:09 p.m.

To:
cc:
bcc:

Subject: Additions and Updates to Medsafe's Website from 28 April - 2 May 2014

Additions and Updates to Medsafe's Website from 28 April – 2 May 2014

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

ABOUT MEDSAFE

Vacancies

Advisor/Senior Advisor (Science), Pre-Market Medicines Assessment

CONSULTATIONS

Outcome of Consultation Topics

Outcome of consultation on the planned changes to the prescribing restrictions for clozapine

CONSUMER MEDICINE INFORMATION

New - Coldrex Hot Remedy Cold & Flu Plus with Decongestant Hot, Difucid tablet

Updated - Atacand tablet, Celapram tablet, FML eye drops solution, HBvaxPRO vaccine solution for injection, Lamivudine Alphapharm tablet, Lanzol Relief capsule, Omezol Relief capsule, Plaquenil tablet, Sinemet CR tablet, Sinemet tablet, Sutent capsule, Vedafilet tablet, Zarzio solution for injection

DATA SHEETS

New - Difucid tablet

Updated - Aclasta solution for infusion, Amyl Nitrite inhalant, Apo-Bromocriptine capsule, Apo-Bromocriptine tablet, Apo-Prazosin tablet, Arrow – Norfloxacin tablet, Celapram tablet, Cilicaine VK capsule, DBL Cefotaxime Sodium for injection, Epilim EC tablet and liquid solution and intravenous injection solution, Finasteride tablet, HBvaxPRO vaccine solution for injection, Intelence tablet, Janumet tablet, Lamivudine Alphapharm tablet, Lanzol Relief capsule, Mersyndol tablet, Mycobutin capsule, Naropin with Fentanyl infusion, Nexium tablet, Plaquenil tablet, Polyvisc eye ointment, Reyataz capsule, Ropin tablet, Sinemet CR tablet (new formulation), Sinemet CR tablet (old formulation), Sinemet tablet (new formulation), Sinemet tablet (old formulation), Sutent capsule, Tobrex eye drops solution, Vedafilet tablet, Xgeva solution for injection, Ziagen oral solution, Ziagen tablet

MEDICINES

Biosimilars

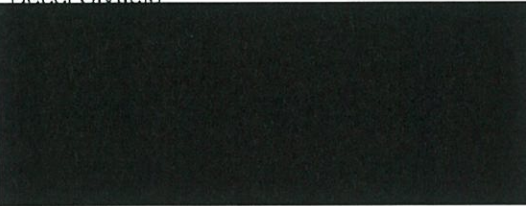
Medsafe's Position on Biosimilars has been updated

Restrictions on the Supply, Prescribing or Administration of Medicines under the

Medicines Act 1981 and Misuse of Drugs Regulations 1977
Clozapine has been updated

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Becci Slyfield



<http://www.medsafe.govt.nz>



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13/05/2014 04:20 p.m.

To:
cc:
bcc:

Subject: Additions and Updates to Medsafe's Website from 5 - 12 May 2014

Additions and Updates to Medsafe's Website from 5 - 12 May 2014

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

COMMITTEES

Medicines Assessment Advisory Committee

Vacancies

The application date has been extended to 13 June 2014

CONSUMER MEDICINE INFORMATION

New - Coldrex PE Phenylephrine Congestion Clear, Montelukast Actavis tablet, Ovidrel solution for injection (pen-filled pen), Reutenox tablet,

Updated - Antabuse tablet, Anten capsule, Apo-Ropinirole tablet, Asamax suppository, Asamax tablet, Beta Scalp Application, scalp lotion, Dopress capsule and tablet, Epilim intravenous, Epilim syrup and tablet and oral solution, Fluox capsule and tablet, Kaletra solution and tablet, Loette tablet, Lucentis solution for injection, Madopar tablet, Mirena intrauterine contraceptive device, Monofeme tablet, Neo-Mercazole tablet, Nexavar tablet, Norvir solution and tablet, Protos granules for oral suspension, Quetapel tablet, Rizamelt tablet, Stesolid rectal tubes, Zolofit tablet, Zypine tablet

DATA SHEETS

New - DBL Magnesium Sulfate solution for injection, Juvederm Hydrate injection solution, Montelukast Actavis tablet, Ovidrel solution for injection (pen-filled pen), Plasmalyte infusion solution, Reutenox tablet

Updated - Anten capsule, Apo-Ropinirole tablet, Aropax tablet, Arrow-Fluoxetine capsule and tablet, Arrow-Sumatriptan injection solution, Asamax 500 suppository, Asamax 500 tablet, Beta Scalp Application, scalp lotion, Calcium Chloride (AFT) injection solution, Celapram tablet, Diamide capsule, Diprosone OV topical cream and ointment, Diprosone topical cream and ointment, Donepezil tablet, Dopress capsule and tablet, Doxorubicin Ebewe concentrate for injection, Forthane volatile liquid for inhalation, Havrix 1440 and Havrix Junior injection suspension, Imigran injection, Imigran tablet, Inlyta tablet, Kaletra solution and tablet, Kliogest tablet, Loette tablet, Madopar tablet and capsule, Maxalt and Maxalt Melt Wafer, Maxalt tablet, Maxidex eye drops suspension, Mencevax ACWY vaccine injection, Mirena intrauterine contraceptive device, Monofeme tablet, Naramig tablet, Nexavar tablet, Norvir solution and tablet, Oruvail SR capsule, Protos granules for oral suspension, Quetapel tablet, Sevorane volatile liquid for inhalation, Synagis injection, Trisequens tablet, Tykerb tablet, Typerix injection suspension, Voltaren Ophtha eye drops

solution

MEDICINES

Forms and Templates

The following forms have been updated as part of the annual review. Only minor changes have been made to improve clarification:

- Declaration to accompany a CMI submitted for publication (*Microsoft Word document 46KB*)
- Drug Master File / Plasma Master File / Certificate of Suitability (*Microsoft Word 48KB*)

SAFETY INFORMATION

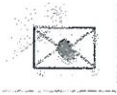
Trans-Tasman Early Warning System

Provide MCT - LCT 1% Emulsion for Injection (10mg/mL) and Provide 1% Emulsion for Injection (10mg/mL) - investigation of infection in Australia

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Becci Slyfield

<http://www.medsafe.govt.nz>



Sent by: Becci Slyfield/MOH

26/03/2015 04:37 p.m.

To: Becci Slyfield/MOH@MOH,
cc:
bcc:

Subject: Additions to the Medsafe Website from 16 - 23 March 2015

Additions to the Medsafe Website from 16 - 23 March 2015

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION

New – Silvasta tablet

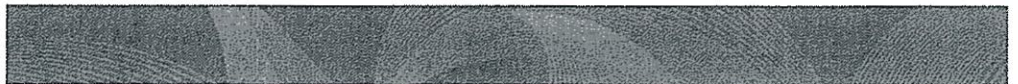
Updated – Epilim intravenous, Epilim syrup and tablet and Modified release tablet and oral solution, Rulide D tablet, Zostavax Zoster virus vaccine

DATA SHEETS

Updated – Aratac tablet, Avastin injection concentrated, Bactroban topical ointment, Epilim syrup and tablet and Modified release tablet and oral solution and intravenous injection solution, Epilim tablet and oral solution and solution for injection and syrup, Kivexa tablet, Neulastim injection solution, Neupogen injection solution, Omezol Relief capsule, Phenergan tablet and elixir, Picosalax powder, Plavix tablet, Proctosedyl ointment and suppository, Rulide D tablet, Serenace liquid oral solution, Tivicay tablet, Xeomin injection powder, Zostavax Zoster virus vaccine

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Becci Slyfield | Clinical Trial Co-ordinator/Web Publishing | Clinical Risk Management | Medsafe | Ministry of Health | +64 4 819 6855 | becci_slyfield@moh.govt.nz | www.medsafe.govt.nz





07/04/2015 02:32 p.m.

To:
CC:
bcc:

Subject: Additions to the Medsafe Website from 30 March - 7 April 2015

Additions to the Medsafe Website from 30 March – 7 April 2015

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

CONSULTATIONS

Current Consultation Topics

Guideline on the Regulation of Therapeutic Products in New Zealand. Part 8: Pharmacovigilance

CONSUMER MEDICINE INFORMATION

New - Fluquadri and Fluquadri Junior suspension for injection, Jakavi tablet

Updated – Bactroban ointment, Dermal cream and ointment, Efexor-XR capsule, Fucithalmic eye drops, Imuprine tablet, Logem tablet, Maxidex eye drops, Stivarga tablet, Tafinlar capsule, Ultiva powder, Ursosan capsule

DATA SHEETS

New – Jakavi tablet, PipTaz-AFT injection powder

Updated – Beconase Allergy & Hayfever 12 hour nasal spray, Celapram tablet, Dermal topical cream and ointment, Epilim EC tablet and oral solution and solution for injection and modified release tablet and syrup, Fluquadri and Fluquadri Junior suspension for injection, Forxiga tablet, Imuprine tablet, Logem tablet, Maxidex eye drops, Stivarga tablet, Tafinlar capsule, Tisseel topical solution, Ursosan capsule, Victrellis capsule, Zelboraf tablet, Zeldox capsule, Zeldox IM powder for injection

SAFETY INFORMATION

Medsafe surgical mesh implant events report updated to April 2015

Monitoring Communication

Guaifenesin (guaiphenesin) and possible risk of tinnitus added to the medicines monitoring scheme

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07/10/2015 03:03 p.m.

To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

Subject: Additions to the Medsafe Website from 28 September - 2 October 2015

Additions to the Medsafe Website from 28 September – 2 October 2015

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

ABOUT MEDSAFE

What is Medsafe?

This page has been updated to reflect changes in the organisational structure of Medsafe

COMMITTEES

Medicines Adverse Reactions Committee

Minutes of the 163rd Medicines Adverse Reactions Committee meeting - 10 September 2015

CONSUMER MEDICINE INFORMATION

New - Vimizim concentrate for infusion

Updated - Implanon NXT subcutaneous implant, Sandomigran tablet, Xalkori capsule

DATA SHEETS

New - Flumazenil injection solution, Vimizim concentrate for infusion, ViruPOS eye ointment

Updated - Abilify tablet, Atacand tablet, Avonex injection with diluent and solution with diluent and Avonex Pen solution for injection, Concerta tablet, Fampyra tablet, Frumil tablet, Glaumox powder for injection, Implanon NXT subcutaneous implant, Perfalgan solution for injection, Perjeta injection concentrate, Remicade powder for infusion concentrate, Sandomigran tablet, Symbicort powder for inhalation, Tecfidera capsule, Tramal oral drops and solution for injection and capsules and SR modified release tablet, Tysabri solution for infusion, Xalkori capsule

SAFETY INFORMATION

Alert Communication

Use of sodium valproate (Epilim) in pregnancy

Surgical Mesh Implants

Medsafe surgical mesh implant events report - October 2015 (PDF 758 KB, 21 pages)

Trans-Tasman Early Warning System

[Audit of the first 12 months of the early warning system \(PDF, 350KB, 14 pages \)](#)

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15/12/2015 11:45 a.m.

To:
cc:
bcc:



Subject: Additions to the Medsafe Website from 7-11 December 2015

Additions to the Medsafe Website from 7-11 December 2015

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION

New – Apo-Riluzole (riluzole) tablet, Desferal (deferoxamine) powder for injection, Sertraline Actavis (sertraline) tablet

Updated – Coldrex PE (paracetamol; phenylephrine) Phenylephrine Congestion Clear, Coldrex PE (paracetamol; phenylephrine) Phenylephrine Sinus, Eumovate (clobetasone) topical cream (restricted), Gadovist (gadobutrol) solution for injection, Omezol Relief (omeprazole) capsule, Vfend (voriconazole) tablet and powder for injection and powder for oral suspension, Zyprexa Relprevv (olanzapine) powder for injection

DATA SHEETS

New - Apo-Riluzole (riluzole) tablet, Desferal (deferoxamine) powder for injection, Sertraline Actavis (sertraline) tablet

Updated – Acilin (sulindac) tablet, Ativan (lorazepam) tablet, Dapsone (dapsone) tablet, Epilin (valproic acid) tablet and intravenous solution for injection and liquid oral solution and syrup, Flixotide (fluticasone) Aerosol inhaler and Flixotide Junior (fluticasone) aerosol inhaler, Flixotide Accuhaler (fluticasone) powder for inhalation, Gadovist (gadobutrol) solution for injection, Isoptin (verapamil) tablet, Isoptin (verapamil) solution for injection, Nardil (phenelzine) tablet, Nurofen Plus (codeine phosphate hemihydrate and ibuprofen) tablet, Omezol Relief (omeprazole) capsule, Remicade (infliximab) powder for infusion concentrate, Seretide Accuhaler (fluticasone; salmeterol) powder for inhalation, Syntocinon (oxytocin) solution for injection

PUBLICATIONS

Prescriber Update

Prescriber Update Vol. 36 No. 4 - December 2015 has been added

SAFETY

Alerts

Dear Healthcare Professional Letters

Tarceva (PDF 91 KB, 2 pages) - Indication restricted to EGFR-activating mutations only

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Health. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. If you no longer wish to receive these emails please send an email to becci_slyfield@moh.govt.nz with unsubscribe in the subject line

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18/04/2016 04:11 p.m.

To:
cc:
bcc:



Subject: Additions to the Medsafe Website from 11-15 April 2016

Additions to the Medsafe Website from 11-15 April 2016

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION		
New		
Tradename	Active ingredient(s)	Dose form
Maxiclear Hayfever & Sinus Relief	loratadine; phenylephrine	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Tamiflu	oseltamivir	capsule
Avonex	interferon beta-1a	injection
Zeffix	lamivudine	oral solution
Varilrix vaccine	varicella vaccine	injection
Clindamycin ABM	clindamycin	capsule
Haldol	haloperidol	injection
Haldol concentrate	haloperidol	injection
Voltaren	diclofenac	injection
Voltaren	diclofenac	suppository
Voltaren	diclofenac	tablet
Voltaren SR	diclofenac	tablet
Voltaren D	diclofenac	tablet
Tamiflu	oseltamivir	oral suspension
Aratac	amiodarone	tablet
Infanrix IPV	diphtheria vaccine; pertussis vaccine; poliomyelitis vaccine; tetanus vaccine	injection
Gadovist	gadobutrol	injection
Revolade	eltrombopag	tablet
Saizen 3	somatropin	injection
Saizen 8	somatropin	injection

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose form
Levomepromazine Hydrochloride (Wockhardt)	levomepromazine hydrochloride	injection
Sodium Valproate	sodium valproate	injection
Zoledronic Acid	zoledronic acid	infusion
Cardioplegia Solution A	calcium chloride; magnesium chloride; potassium chloride; sodium chloride	solution
Etoposide (Rex Medical)	etoposide	injection
Updated		
Tradename	Active ingredient(s)	Dose form
Tobradex	tobramycin; dexamethasone	eye drops
Prevenar 13	pneumococcal polysaccharide conjugate vaccine	injection
Tamiflu	oseltamivir	capsules oral suspension
Synthroid	levothyroxine sodium	tablet
Avonex	interferon beta-1a	injection
Colofac	mebeverine hydrochloride	tablet
Clindamycin ABM	clindamycin hydrochloride	capsule
Ikorel	nicorandil	tablet
Caelyx	pegylated liposomal doxorubicin hydrochloride	infusion
Varilrix vaccine	varicella vaccine	injection
Haldol	haloperidol	injection
Haldol concentrate	haloperidol	injection
Voltaren	diclofenac	injection
Voltaren	diclofenac	suppository
Voltaren	diclofenac	tablet
Voltaren SR	diclofenac	tablet
Voltaren D	diclofenac	tablet
Zoloft	sertraline	tablet
Verorab	rabies vaccine	injection
Imigran	sumatriptan	injection
Imigran	sumatriptan	tablet
Revolade	eltrombopag	tablet
Saizen 3	somatropin	injection
Saizen 8	somatropin	injection
Gadovist	gadobutrol	injection
Deleted		

Tradename	Active ingredient(s)	Dose form
Gelafusal	succinic anhydride gelatin	infusion

COMMITTEES

Medicines Classification Committee

Comments on agenda items for the 55th Medicine Classification Committee Meeting

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To: [Redacted]
 cc: [Redacted]
 bcc: [Redacted]

03/08/2016 04:07 p.m.

Subject: Additions to the Medsafe Website from 25 July-2 August 2016

Additions to the Medsafe Website from 25 July-2 August 2016

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION		
New		
Tradename	Active ingredient(s)	Dose form
Gardasil 9	Human Papillomavirus 9-valent Vaccine Recombinant	injection
Ozurdex	dexamethasone	
Paracetamol Kabi	paracetamol	injection
Proveblue	methylene blue (as trihydrate)	injection
Updated		
Tradename	Active ingredient(s)	Dose form
Afinitor	everolimus	tablet
Antabuse	disulfiram	tablet
Arrow Amitriptyline	amitriptyline hydrochloride	tablet
Arrow-Quinapril	quinapril	tablet
Cerazette	desogestrel	tablet
Dilantin	phenytoin phenytoin sodium	capsule tablet oral suspension
Glucose 5% Freeflex	glucose monohydrate	infusion
Kalydeco	ivacaftor	tablet
Tilcotil	Tenoxicam	tablet
Varivax	varicella virus vaccine live (Oka/Merck)	injection
Zetop	cetirizine hydrochloride	tablet
Ziagen	abacavir sulphate	oral solution

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose form

Gardasil 9	Human Papillomavirus 9-valent Vaccine, Recombinant	injection
Paracetamol Kabi	paracetamol	injection
Proveblue	methylene blue (as trihydrate)	injection
Tobramycin Mylan	Tobramycin	injection
Zista	Cetirizine hydrochloride	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Afinitor	everolimus	tablet
BICNU	carmustine	injection
Cerazette	desogestrel	tablet
Cervidil	dinoprostone (prostaglandin e2)	vaginal pessary
Cubucin	daptomycin	infusion
Dilantin	phenytoin phenytoin sodium	capsule tablet oral suspension
Epilim	Sodium valproate	tablet injection liquid oral solution syrup
Erivedge	vismodegib	capsule
Extraneal	icodextrin	solution
Glucose 5% Freeflex	glucose monohydrate	infusion
Kalydeco	ivacaftor	tablet
Logem	lamotrigine	tablet
Premarin	conjugated estrogens	tablet
Premia	conjugated estrogens and medroxyprogesterone acetate	tablet
Tamiflu	Oseltamivir	oral suspension capsule
Varivax	varicella virus vaccine live (Oka/Merck)	injection
VPRIV	velaglucerase alfa	infusion
Zetop	cetirizine hydrochloride	tablet
Ziagen	abacavir sulphate	oral solution

COMMITTEES

Medicines Adverse Reactions Committee

Minutes of the 166th Medicines Adverse Reactions Committee Meeting - 29 June 2016

DIETARY SUPPLEMENTS

Regulation of Dietary Supplements

Application Form for an Export Certificate for Dietary Supplements (PDF 101kb, 2 pages) has been updated.

PUBLICATIONS

Prescriber Update

Prescriber Update Reader Satisfaction Survey July 2016 - Survey Outcome Report (PDF 4024 KB, 17 pages)

SAFETY

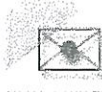
Alerts

Early Warning System Alert Communications

Quickie Q7 Wheelchair (Model ER14) manufactured between 1 September 2009 & 27 November 2013. (Backrest Bracket Damage)

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09/01/2017 05:30 p.m.

To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

Subject: Additions to the Medsafe Website from 5 December 2016 - 6 January 2017

Additions to the Medsafe Website from 5 December 2016 - 6 January 2017

This email is to inform you of recent additions and updates to the Medsafe website.

COMMITTEES

Medicines Adverse Reactions Committee

Medicines Adverse Reactions Committee - Minutes for the 168th Meeting - 1 December 2016

Medicines Classification Committee

Medicines Classification Committee - Recent Gazette Notices

Medicines Classification Committee - Dates and Deadlines

MEDICAL DEVICES

Update: Implementation of Government Response to Report of the Health Committee on Petition 2011/102

Reporting Adverse Events Associated With Medical Devices

PUBLICATIONS

Information for Women with Breast Implants

Prescriber Update

Vol. 37 No. 4 - December 2016

Answers to the Prescriber Update Quiz - December 2016

SAFETY INFORMATION

Update to Monitoring Communication

EasyCheck hCG Urine Pregnancy Test Cassette – Invalid (Negative) and Inconclusive Results

Alert Communication

Consumer Level Recall – Pivot, Pivot Hygiene, Pivot Hammock and Tony Pringle clip style sling used for patient hoists

CONSUMER MEDICINE INFORMATION

New		
Tradename	Active ingredient(s)	Dose form
Copegus	ribavirin	tablet
Finasteride (Pharmacare) 1mg	finasteride	tablet
Finasteride (Pharmacare) 5mg	finasteride	tablet
Noradrenaline BNM	noradrenaline	injection

One Alpha	alfacalcidol	capsule oral drops
Rheumon	etofenamate	topical gel
Sativex	cannabidiol; tetrahydrocannabinol	oral spray
Zepatier	elbasvir; grazoprevir	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Beclazone	beclometasone	cfc-free in inhaler
Benzac AC	benzoyl peroxide	topical gel
Brilinta	ticagrelor	tablet
Cardizem and Cardizem CD	diltiazem	capsule tablet
Clobex	clobetasol	shampoo
Depo-Provera	medroxyprogesterone	injection
Enbrel	etanercept	injection
Epiduo	adapalene; benzoyl peroxide	gel
Epilim	valproic acid	injection
Epilim and Epilim EC	valproic acid	tablet liquid solu syrup
Erivedge	vismodegib	capsule
Estradol	estradiol	transderm
Eviplera	emtricitabine; rilpivirine; tenofovir	tablet
FluQuadri and FluQuadri Junior	influenza vaccine polyvalent	injection
Imbruvica	ibrutinib	capsule
Influvac	influenza vaccine polyvalent	injection
Klacid	clarithromycin	tablet oral suspe injection modified r
Konakion MM and Konakion MM Paediatric	phytomenadione	injection
Marvelon 28	desogestrel; ethinylestradiol	tablet
Mercilon 28	desogestrel; ethinylestradiol	tablet
Metvix	methyl aminolevulinate	cream
MMR II Vaccine	measles vaccine; mumps vaccine; rubella vaccine	injection

NuvaRing	ethinylestradiol; etonogestrel	vaginal rin
Polaramine	dexchlorpheniramine	tablet
Postinor-1	levonorgestrel	tablet
Provera and Provera HD	medroxyprogesterone	tablet
Revlimid	lenalidomide	capsule
Rifadin	rifampicin	capsule
Sutent	sunitinib	capsule
Thalomid	thalidomide	capsule
Tramadol Hydrochloride	tramadol	capsule
Vaxigrip	influenza vaccine polyvalent	injection
Vttack	voriconazole	tablet

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose fo
Allmercap	mercaptapurine	oral sus
Apo-Paroxetine	paroxetine	tablet
Finasteride (Pharmacare) 1mg	finasteride	tablet
Finasteride (Pharmacare) 5mg	finasteride	tablet
Noradrenaline BNM	noradrenaline	injectior
One Alpha	alfacalcidol	capsule
		oral dro
Rheumon	etofenamate	topical g
Zepatler	elbasvir; grazoprevir	tablet
Updated		
Tradename	Active ingredient(s)	Dose fo
Abilify	aripiprazole	tablet
Angiomax	bivalirudin	injectior
Angiomax	bivalirudin	injectior
Beclazone	beclometasone	cfc-free
		inhaler
Brilinta	ticagrelor	tablet
Cafergot	caffeine; ergotamine	tablet
Cardizem	diltiazem	tablet
Cardizem CD	diltiazem	capsule
Concerta	methylphenidate	tablet
Creon	pancreatin	capsule
Depo-Provera	medroxyprogesterone	injectior
Depo-Testosterone	testosterone	injectior
Dexamethasone	dexamethasone	injectior
Effient	prasugrel	tablet

Enbrel	etanercept	injectior
Epilim and Epilim EC	valproic acid	tablet
		injectior
		oral soli
		syrup
EpiPen and EpiPen Junior	adrenaline	injectior
Erivedge	vismodegib	capsule
Esbriet	pirfenidone	capsule
Estradot	estradiol	transde
Eviplera	emtricitabine; rilpivirine; tenofovir	tablet
FluQuadri and FluQuadri Junior	influenza vaccine polyvalent	injectior
Gonal-F	follitropin	injectior
Imbruvica	ibrutinib	capsule
Influvac	influenza vaccine polyvalent	injectior
Isoptin	verapamil	injectior
Klacid	clarithromycin	tablet
		oral sus
		injectior
		modifie
Konakion MM and Konakion MM Paediatric	phytomenadione	injectior
Marvelon 28	desogestrel; ethinylestradiol	tablet
MMR II Vaccine	measles vaccine; mumps vaccine; rubella vaccine	injectior
Naüzene	cyclizine	tablet
Noxafil	posaconazole	tablet
NuvaRing	ethinylestradiol; etonogestrel	vaginal
Otezla	apremilast	tablet
Pentacarinat	pentamidine	injectior
Polaramine	dexchlorpheniramine	tablet
Postinor-1	levonorgestrel	tablet
Provera and Provera HD	medroxyprogesterone acetate	tablet
Reminyl	galantamine	capsule
Risperdal and Risperdal Quicklet	risperidone	tablet
Rytmonorm	propafenone	tablet
Simponi	golimumab	injectior
Strattera	atomoxetine	capsule
Suboxone	buprenorphine; naloxone	tablet
Sutent	sunitinib	capsule

Temgesic	buprenorphine	injectior
Thalomid	thalidomide	capsule
Tramadol Hydrochloride	tramadol	capsule
Vaxigrip	influenza vaccine polyvalent	injectior
Vttack	voriconazole	tablet
Zerbaxa	ceftolozane; tazobactam	injectior
Zyprexa	olanzapine	injectior
Zyprexa and Zyprexa Zydis	olanzapine	tablet
		wafer
Zyprexa Relprevv	olanzapine	injectior

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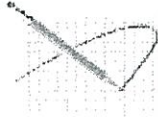
Becci Slyfield



<http://www.medsafe.govt.nz>



OFFICIAL INFORMATION ACT



Sent by:

[Redacted]

To: [Redacted]

cc:

bcc:

16/07/2001 12:49 p.m.

Subject: Additions to Medsafe's Web site 9 July - 13 July 2001

Additions to Medsafe's Web site 9 July - 13 July 2001

<http://www.medsafe.govt.nz/indexie4.htm>

<http://www.medsafe.govt.nz/indexother.htm>

INFORMATON FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Cytotec, Danocrine, Diflucan, Diflucan IV, Epilim injection, Eryc, Glytrin, Micanol, Norflex, Pancrease, Reminyl, Resonium A, Somac, Vesanoid, Zithromax

Updated - Cellcept, Epilim, Relenza, Zenapax, Zyban

Datasheets - <http://www.medsafe.govt.nz/Profs/Datashcet/DSForm.asp>

New - Aciclovir, Bleomycin Sulfate, Cefuroxime Sodium, Cociois, Crystacide, Cytotec, Daunorubicin Hydrochloride, Dobutamine Hydrochloride, Doxorubicin Hydrochloride, Edetate Disodium, Haloperidol Decanoate, Naloxone Hydrochloride, Miflasone, Pacific Cefaclor, Phenoxymethylpenicillin, Zostrix

Updated - Avonex, Betaloc CR, Cordarone X, Flomax 0.4, Infanrix-IPV, Solu Medrol, Sporanox capsules, Sporanox oral solution, Trileptal, Visudyne, Zanidin

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette notice for 12 July 2001 added

28/02/2003 12:31 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 24-28 February 2003

Additions to Medsafe's Web site from 24-28 February 2003

INFORMATION FOR CONSUMERS

Support Groups - <http://www.medsafe.govt.nz/Consumers/support.htm>

The contact details for Diabetes NZ has been changed

INFORMATION FOR HEALTH PROFESSIONALS

Adverse Reaction Reporting and IMMP -

<http://www.medsafe.govt.nz/Profs/adverse/Minutes112.htm>

The Minutes of the 112th Medicines Adverse Reactions Committee meeting have been added

Classification of Medicines

The dates and deadlines have been updated -

<http://www.medsafe.govt.nz/Profs/class/dates.htm>

The Agenda for the 29th Medicines Classification Committee meeting has been added

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Lantus

Updated - Agenerase, Elocon, Epilim IV, Epilim tablets & syrup & liquid, Estraderm TTS, Flixotide accuhaler, Flixotide aerosol inhaler, Flixotide CFC-free inhaler, Gentamicin, Monofeme 28, Nizoral, Nordette 21, Nordette 28, Nordiol 21, Pegasys, Permax, Seretide accuhaler, Seretide inhaler, Serevent accuhaler, Topamax, Trifeme 28, Triphasil 28, Zyban

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 27 February 2003 has been added

Guidelines & Codes - New Zealand Regulatory Guidelines for Medicines -

<http://www.medsafe.govt.nz/Regulatory/Guideline/medicines.htm>

The contact details for the Chairman of SCOTT have been changed

Becci Slyfield

<http://www.medsafe.govt.nz>

[Redacted]

To: [Redacted]
cc: [Redacted]
bcc:

07/03/2003 03:56 p.m.

Subject: Additions to Medsafe's Web site from 3-7 March 2003

Additions to Medsafe's Web site from 3-7 March 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Qvar autohaler, Qvar inhaler

Updated - Accuretic, Arcoxia, Epilim, Midamor, Nizoral, Noroxin, Singulair, Xenical

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apatef, Celapram, Cromolux, Dynastat, Fucifthalmic, Ledertrexate

Updated - D-Zol, Headway, Intragam P, Logoderm, Mabthera, Nicorette gum, Nicorette inhaler 10mg, Nicorette patch, Nicotrol, Nordiol 21, Noroxin, Plinzene, Progout, Pulmozyme, Roferon A, Spirotone, Staphlex, Tazocin, Trichazole

REGULATORY INFORMATION

Gazette Notices - **<http://www.medsafe.govt.nz/Regulatory/gazette.asp>**

Gazette Notice for 6 March 2003 has been added

Becci Slyfield

[Redacted]

<http://www.medsafe.govt.nz>

[Redacted]

[REDACTED]
17/04/2003 04:15 p.m.

To: [REDACTED]
cc: [REDACTED]
bcc: [REDACTED]

Subject: Additions to Medsafe's Web site from 14-17 April 2003

Additions to Medsafe's Web site from 14-17 April 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Recormon, Betaferon

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

Updated - Actilyse, Augmentin, Betaferon, Epilim, Fosamax, Lipex, Nordiol 21, Trental, Vioxx, Zeffix oral solution, Zeffix tablets

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

The Gazette Notice for 17 April 2003 has been added

Becci Slyfield
[REDACTED]

<http://www.medsafe.govt.nz>
[REDACTED]

OFFICIAL INFORMATION ACT
USED UNDER THE

17/08/2007 03:53 p.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 4-8 August 2003

Additions to Medsafe's Web site from 4-8 August 2003

HOT TOPICS

Media Releases - <http://www.medsafe.govt.nz/Hot/Media/2007/ANZTPA.asp>
The Therapeutics Products and Medicines Bill has been postponed

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Arava, Byetta

Updated - Crixivan, RotaTeq, Sumagran

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Prof/ Datasheet/DSForm.asp>

New - Aquamid, Byetta,

Updated - Arava, Avandia, Crixivan, Dobutamine in 5% Dextrose, Epilim, Epilim IV, Fluvax, Invanz, RotaTeq, Solian

REGULATORY INFORMATION

Guidelines & Codes - <http://www.medsafe.govt.nz/regulatory/guidelines.asp>

Appendix 4: Checklist for New Prescription Medicine Applications (CTD) - effective from 17 August 2007

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.anztpa.org>

There are no updates to this site this week

Becci Slyfield

<http://www.medsafe.govt.nz>

RELEASED UNDER THE OFFICIAL INFORMATION ACT

28/11/2003 05:18 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 24-28 November 2003

Additions to Medsafe's Web site from 24-28 November 2003

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/emi/CMIForm.asp>

New - Concerta, Hygroton, Isotane

Updated - Aricept, Epilim, Kemadrin, Maxolon, Resonium-A

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Moclobemide, Cetrotide,

Updated - Anafranil, BeneFix, Bicillin L-A Tubex, Brondecon Elixir, Clane, Climara 50 and Climara 100, Nuvelle, Prinivil, Progynova, Xylocard 100 and Xylocard 500

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/Regulatory/consultants.htm>

This has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 27 November 2003 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

10/05/2004 03:46 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 3-7 May 2004

Additions to Medsafe's Web site from 3-7 May 2004

HOT TOPICS

Alerts/Letters - <http://www.medsafe.govt.nz/hot/RecallMay04.htm>

Information on a consumer recall of contaminated products has been added

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Adenocor, Calcium Resonium, Cordarone X, Dancorine, Epilim oral, Fortral, Plaquenil, Plavix, Primacor, Resonium A

Support Groups - <http://www.medsafe.govt.nz/Consumers/support.htm#Alzheimer's>
The Alzheimers New Zealand contact details have been updated

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Azopt, Min-I-Jet Lignocaine Hydrochloride (CSL)

Updated - Aldara, Adrenaline Hydrochloride Min-I-Jet (CSL), Aspro, Avaxim, Cancidas, Cefazolin, Cialis, Dysport, Herceptin, Innohep, IPOL, Lipex, Marcain Dental with Adrenaline, Seretide Inhaler, Synacthen, Synacthen Depot, Zelmac

Prescriber Update Articles - <http://www.medsafe.govt.nz/Profs/PUarticles/Statinmyop.htm>
An article entitled Myopathy with Statins: Check CK Levels and Interactions has been added

OTHER INFORMATION

Vacancies - <http://www.medsafe.govt.nz/Other/vacancyTLC.htm>
A vacancy for a Team Leader Medicines Control has been added

Becci Slyfield



<http://www.medsafe.govt.nz>



OFFICIAL INFORMATION ACT

05/09/2005 11:02 a.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 29 August-2 September 2005

Additions to Medsafe's Web site from 29 August-2 September 2005

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Femtran, Provera, Provera HD

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Clarac, Stromectol

Updated - Celapram, Dantrium IV, Drolectan, Epikim IV, Epilim (tablets, liquid and syrup), Fluox, Fosamax, Invanz, Iressa, Ismo 20, Lexapro, Relenza, Rifadin, Rifinah, TMP, Vaqta

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 2 September 2005 has been added

GMP Certified Contract Testing Laboratories -

This page has been updated

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.tgamedsafe.org>

There are no updates this week.

Becci Slyfield

<http://www.medsafe.govt.nz>

20/01/2006 06:01 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 9-20 January 2006

Additions to Medsafe's Web site from 9-20 January 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Vaxigrip Junior

Updated - Cialis, Ethyol, Ezetrol, Invirase, Ketalar, Noroxin, Primaxin, Stamaril, Stengen, Vaxigrip

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The outcome of the December 2005 out-of-session consultation with the MCC is now available. The recommendations have been accepted by the Minister's Delegate. Medsafe agrees with these recommendations. It is intended that the changes should be notified in the Gazette on 2 March 2006.

Intention to object to any of these recommendations should be lodged with the MCC secretary no later than 3 February 2006 and should be together with a statement of the safety grounds on which the objection is based. See Dates and Deadlines for the closing date to submit supporting safety data for objections.

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Avastin, Cefazolin injection and Cefazolin Sandoz, Polaramine, Zadine

Updated - Aromasin, Cromolux, Dilantin, Epilim, Ezetrol, Gopten, HBvaxPRO, Isoptin injection, Isoptin and Isoptin SR tablets, Noroxin, Odrik, Pentasa, Primaxin, Prostin VR, Ufexil, Xalacom, Xalatan, Zofran injection, Zofran tablets, Zofran Zydis

Interchangeable Status - <http://www.medsafe.govt.nz/Profs/imm.htm>

List of Interchangeable Multi-Source Medicines has been updated

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 12 and 19 January 2006

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

<http://www.tgamedsafe.org/>

There has been a change to the information on the home page under 'Introduction to the project'

Becci Slyfield

20/02/2006 05:32 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13-17 February 2006

Additions to Medsafe's Web site from 13-17 February 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Cromolux, Fortovase, MeNZB, Primacor, Stromectol

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - DP-Risperidone

Updated - AliMTA, Elocon, Epilim IV, Fluvax, Fucidin, m-Eslon, MeNZB, Multiload, Rapamune, Reductil, Skincalm, Stromectol, Varivax, Vytorin, Zyprexa IM

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/Regulatory/consultants.htm>

This list has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 9 February 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.jtaproject.com

There are no updates to this site this week

Becci Slyfield

<http://www.medsafe.govt.nz>

[REDACTED]
17/03/2006 04:40 p.m.

To: [REDACTED]
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13-17 March 2006

Additions to Medsafe's Web site from 13-17 March 2006

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Epilim IV

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Trileptal oral suspension, Vermox

Updated - Avastin, Biostate, Ipratropium Steri-Neb, Pneumovax 23, Risperdal, Teril, Topamax, Trileptal tablets

List of Interchangeable Multi-source Medicines -

<http://www.medsafe.govt.nz/Profs/imm.htm>

This list has been updated:

New - Lamotrigine

Updated - Doxazosin, Terbinafine

REGULATORY INFORMATION

GMP Certified Contract Testing Laboratories -

<http://www.medsafe.govt.nz/Regulatory/contractTesting.htm>

This list has been updated.

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 16 March 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.tgamedsafe.org

There are no updates to this site this week

Becci Slyfield
[REDACTED]

<http://www.medsafe.govt.nz>
[REDACTED]

07/04/2006 05:23 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 27 March - 7 April 2006

Additions to Medsafe's Web site from 27 March - 7 April 2006

HOT TOPICS

Alerts/Letters - Unapproved prescription and pharmacist-only medicines from China - April 2006

Director-General's Statement Under Section 98 of the Medicines Act 1981 -

<http://www.medsafe.govt.nz/hot/Alerts/ChineseMed/DGStatement.htm>

Photos of Unapproved prescription and pharmacist-only medicines from China -

<http://www.medsafe.govt.nz/hot/Alerts/ChineseMed/Photos.htm>

Consultation - ANZTPA - <http://www.medsafe.govt.nz/hot/TTCconsultation.htm>

A Consultation programme released for the establishment of the Australia New Zealand Therapeutic Products Authority has been added

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Colgout, Covensyl Plus, Premarin, Premia, Nordette, Trifeme, Triphasil, Velcade

Updated - Betaferon, Daktarin, Efexor, Efexor-XR, Epilim oral, Herceptin, Loette, Losec, Minulet, Monofeme, Predonium, Recormon, Trileptal

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The agenda for the 35th meeting of the MCC is now available for consultation. A date for the meeting will be published shortly. Interested bodies have until 19 May to submit comments on agenda items. Please note that the remainder of the 34th agenda will also be considered at this meeting and that the consultation for this meeting has already occurred. -

<http://www.medsafe.govt.nz/Profs/class/agen35.htm>

Dates and Deadlines have also been updated -

<http://www.medsafe.govt.nz/Profs/class/dates.htm>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Paroxetine, Heparinised Saline, Lipiodol, m-Cefazolin, Methotrexate Ebewe

Updated - Avandia, Betaferon, Cafergot, Cefazolin and Cefazolin Sandoz, Cefotaxime, Ceftriaxone, Clorotir, Clozaril, Flameril, Flameril Retard, Miochol-E, Norcuron, Orzel, Ospamox, Penicillin G Sodium, Permax, Recormon, Ritalin and Ritalin SR, Seroquel, Zenapax, Zyprexa

Prescriber Update Articles

Leflunomide and Pneumonitis -

<http://www.medsafe.govt.nz/Profs/PUarticles/LeflunLung.htm>

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 30 March and 6 April 2006 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.jtaproject.com

The following NEW information has been added:

- **Child-resistant packaging requirements for therapeutic goods - consultation**
<http://www.anztpa.org/consult/crp.htm>
- **Second meeting of the Joint Interim Expert Advisory Committee on Standards**
<http://www.anztpa.org/committees/jieacs.htm#second>
- **Second meeting of the pharmacopoeial sub-committee of the Joint Interim Expert Advisory Committee on Standards to consider the default standard for the ANZTPA**
<http://www.anztpa.org/committees/jieacs.htm#ps2>

Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE OFFICIAL INFORMATION ACT

14/09/2007 03:41 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 10-14 September 2007

Additions to Medsafe's Web site from 10-14 September 2007

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Tykerb, Voltfast

Updated - Avandia, Cardizem CD, Cellcept, Copaxone, Fosamax Plus, Fuzeon, RotaTeq, Voltaren injection, Voltaren suppositories, Voltaen tablets

Importing Medicines - <http://www.medsafe.govt.nz/Consumers/MIET/ImportMedicines.asp>
A new section on importing medicines has been added

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profis/Datasheet/DSForm.asp>

New - Kenacomb, Tykerb

Updated - Codeine Phosphate, Daclin, Epilim IV, Epilim (tablets, syrup and liquid), Fuzeon, Humira, Rotarix, Saizen, Sporanox capsule, Sporanox oral solution, Tambocor and Tambocor CR, Verpamil and Verpamil SR

REGULATORY INFORMATION

Consultants - <http://www.medsafe.govt.nz/regulatory/consultants.asp>

This list has been updated

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 30 August 2007 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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with unsubscribe in the subject line.

Becci Slyfield

[REDACTED]

To: [REDACTED]
cc: [REDACTED]
bcc:

21/09/2007 04:38 p.m.

Subject: Additions to Medsafe's Web site from 17-21 September 2007

Additions to Medsafe's Web site from 17-21 September 2007

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Imovane

Updated - Azopt, Cardinol LA, Epilim IV, Epilim Oral, Fortovase, Malarone, Meningitec, Naramig, Trasyolol

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Rectogesic

Updated - Atacand, Cataflam, Codeine Phosphate, Copegus, Infanrix-hexa, Kaletra, Naropin, Pegasys, Pegasys RBV, Seroquel, Sumagran Active, Voltaren Rapid

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 16 August and 20 September 2007 have been added

Medical Devices - <http://www.medsafe.govt.nz/Regulatory/MedicalDevices/condoms.asp>
Requirements for Condoms has been added

Medicines Classification Committee

Agenda for 38th Meeting (December 2007) of the Medicines Classification Committee has been added - <http://www.medsafe.govt.nz/profs/class/agen38.htm>

Dates and Deadlines have been updated - <http://www.medsafe.govt.nz/profs/class/dates.asp>

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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Becci Slyfield

[REDACTED]

30/06/2008 11:46 a.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 16-27 June 2008

Additions to Medsafe's Web site from 16-27 June 2008

HOT TOPICS

Alerts/Letters

Eltroxin (levothyroxine) - June 2008

Media Release - <http://www.medsafe.govt.nz/hot/media/2008/Eltroxin.asp>

Dear Dr Letter sent by Medsafe - <http://www.medsafe.govt.nz/hot/alerts/Eltroxin.asp>

Dear Dr Letter sent by GlaxoSmithKline (1329kb this is a pdf document and Acrobat Reader is required for viewing) - <http://www.medsafe.govt.nz/hot/alerts/Eltroxin.pdf>

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Dilantin, Dilatrend, Efexor-XR, Humira, Hypnovel, Loette, Minulet, Neotigason, Synflex, Trifeme, Triphasil, Varivax

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Clopidogrel, Bicalox, Fluorescein

Updated - Apo-Doxazosin, Augmentin, Avandia, Baraclude, Bezalip, Cisplatin (Mayne Pharma), Clopixol, Clozaril, DBL Atracurium Besylate, Dostinex, Elidel, Eloxatin, Epilim IV, Epilim tablets, syrup and liquid, EpiPen, EpiPen Junior, Fluanxol, Genox, Haldol, Humira, Maxalt, Minirin, Modavigil, Neotigason, Nizoral, Norspan, OxyContin, OxyNorm capsules and liquid, OxyNorm injection, Precedex, Prezista, Prostin E2, Pulmozyme, Remicade, Seretide Accuhaler, Seretide Inhaler, Tegretol, Trandate, Trizivir, Zelmec, Zevalin, Ziagen solution, Ziagen tablets, Zyban

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 19 June 2008 has been added

JOINT TRANS-TASMAN THERAPEUTIC PRODUCTS REGULATORY SCHEME:

www.anztpa.org

There are no updates to this site this week

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[REDACTED] with unsubscribe in the subject line.

Becci Slyfield

08/05/2009 03:47 p.m.

To: [REDACTED]
cc: [REDACTED]
bcc:

Subject: Additions to Medsafe's Web site from 4-8 May 2009

Additions to Medsafe's Web site from 4-8 May 2009

HOT TOPICS

Media Releases - <http://www.medsafe.govt.nz/hot/media/2009/teething.asp>
Update on the use of "teething" gels containing choline salicylate in children - results of Medsafe's review

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Efudix, Fexofast

Updated - Diastop, D-Penamime, Flucazole, Fluconazole, Lithicarb FC, Noflam, Nupentin, Tramedo, Trisul-Tabs

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Kenacomb ointment

Updated - Avomine, Brufen syrup, Brufen tablets, Ceenu, Diastop, D-Penamime, Efudix, Epilim IV, Epilim, Eprex, Florinef, Flucazole, Fluconazole, Hepsera, Hiberix, Humira, Imuran, Jadelle, Kabiven G11, Kabiven G19, Kaletra, Kenacomb, Kivexa, Lithicarb FC, MabThera, Megace, Mersyndol, Mycostatin, Neorecormon, Noflam, Nupentins, Questran Lite, Sabril, Tramedo, Trisul, Trizivir, Vesicare

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 8 May 2009 has been added

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Becci Slyfield
[REDACTED]

<http://www.medsafe.govt.nz>
[REDACTED]

15/05/2009 04:36 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 11-15 May 2009

Additions to Medsafe's Web site from 11-15 May 2009

Reminder: Medsafe is seeking feedback on the consultation document - Proposed Changes to the Fees Payable Under the Medicines Regulations 1984. Feedback is requested by **22 May 2009**

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Adalat OROS, Adalat tablets, Angiomax, Arava, Cardinol, Cerazette, Epilim, Epilim IV, Fosmax, Fosmax Once Weekly, Gliben, Headway, Janumet, Januvia, Nasaclear, OncoTICE, Orgalutran, Ovestin cream, Phenate, Piram-D, Sabril, Triamizide, Vesicare, Zetop

INFORMATION FOR HEALTH PROFESSIONALS

Prescriber Update

May 2009 -

http://www.medsafe.govt.nz/profs/PUArticles/PDF/Prescriber%20Update_May09.pdf

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Tygacil, Zetop

Updated - ACB, Amizide, Aratac, Cardinol, Cardizem CD, Clopress, Crinone, Diurin 40, Dopress, Entrel, Ferrum H, Gliben, Headway, Janumet, Januvia, Logem, Martindale Pharma Acetylcysteine, Micreme vaginal cream, Nasaclear, Norvir, Pacific Bupirone out, Phenate, Piram-D, Prog, Remicade, Skincalm, Tambocor, Triamizide

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 14 May 2009 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

11/06/2010 05:01 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 31 May - 11 June 2010

Additions to Medsafe's Web site from 31 May - 11 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Immucyst BCG, Serophene

Updated - Betaferon, Byetta, Dulcolax, Fosamax, Fosamax, Isentress, Lipex, Tareeva, Velcade, Viramune

Re-published in PDF (no changes to content) - Condyline, Etidrate, Genox, Glucobay, Hypam, Lithicarb FC, Lora-tabs, Metamide, Metoclopramide

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Classification Process - <http://www.medsafe.govt.nz/profs/class/classificationprocess.asp>

This page has been updated

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

This page has been updated

Minutes of the Medicines Classification Committee Meetings -

<http://www.medsafe.govt.nz/profs/class/mccMin13April2010.htm>

Minutes of the forty-third meeting of the Medicines Classification Committee - 13 April 2010, have been added

Prescriber Update Articles - <http://www.medsafe.govt.nz/profs/PUarticles.asp>

The June 2010 edition of Prescriber Update, including the following articles have been added

- Dextropropoxyphene withdrawal on 1 August 2010 - a reminder
- Methylphenidate - updated guidance when treating children
- Cough and cold medicines - update and reminder
- Tramadol - key points for prescribing
- Omeprazole and risk of hypomagnesaemia
- Update on rotavirus vaccines
- Interaction: Sodium valproate and carbapenems - new information
- Case report: Stevens-Johnson syndrome associated with the use of allopurinol
- Codeine - classification and labelling changes
- Adverse reactions associated with intra-articular use of local anaesthetics
- Acitretin (Neotigason) - points to remember
- Warfarin - reports of serious adverse reactions continue
- Zoledronic acid associated with adverse effects on renal function
- Medicine recalls
- Alendronate case report - the importance of patient counselling
- Medicine quality complaints

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Apo-Timol, Serophene, Ubistesin forte

Updated - Betaferon, Byetta, Comtan, Fibalip, Fosamax, Immucyst BCG, Imuprine, Isentress, Lipex, Nozinan, Panadol caplets, ReTrieve, Rexacrom, Risperon, Tarceva, Terazosin, Velcade, Vimpat, Xigris, Xylestesin-A

Re-published in PDF (no changes to content) - Aciclovir, Brevinor, Brevinor-1, Condyline, Gentamicin, Glucobay, Lucentis, Noriday, Norinyl-1, Normin, Synphasic

Medical Devices - <http://www.medsafe.govt.nz/profs/device-issues.asp>

Medsafe Statement - Graseby MS-Series Syringe Drivers - Further Extension of Deadline

Regulatory Issues - <http://www.medsafe.govt.nz/profs/RIss/restrict.asp>

The restrictions on the supply of Clozapine have been updated

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 3 June 2010 has been added

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Becci Slyfield

<http://www.medsafe.govt.nz>

18/06/2010 05:09 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 14-18 June 2010

Additions to Medsafe's Web site from 14-18 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Imuprine, ReTrieve,

Updated - Avastin, Camptosar, Januvia, Konakion MM, Loxamine, Madopar

Re-published in PDF (no changes to content) - Adacel, Adacel Polio, Asamax, Asamax 500, Avaxim, Disipal, Dukoral, IPOL, Lemnis Fatty Cream HC, Liposort, Locoid, Locoid C, Menomune ACYW-135, Mildison, Noriday, Norinyl-1 21 day, Norinyl-1 28 day, Pimafucort, Quadracel, Stamaril, Typhim vi, Vivaxim

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

Updated - Avastin, Baraclude, Camptosar, Cefalexin, Epilim and Epilim EC, Epilim intravenous, Fosamax, Genotropin, Gutron, Januvia, Konakion MM, Largactil, Loxamine, Madopar, Spiriva, Zoloft,

Re-published in PDF (no changes to content) - Adacel, Adacel Polio, Advate, Aerrane, Amyl Nitrite, Asacol, Asamax 500 suppository, Asamax 500 tablet, Avaxim, Cal D Forte, Cernevit, Codeine Phosphate, Curam injection, Curam tablet and suspension, Dexamphetamine sulphate, Disipal, Dukoral, Ephedrine Hydrochloride, Extraneal, Feiba NF, Fleet Phospho-Soda, IPOL, Isoniazid, Lemnis Fatty Cream HC, Lipocort, Locoid, Locoid C, Menomune ACYW-135, Methatabs, Midazolam, Mildison Lipocream, Pethidine, Phenobarbitone BP, Pimafucort, Quadracel, Sodium Chloride, Stamaril, Terbinafine-DP, Thalidomide, Typhim Vi, Vivaxim, Voluven

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 17 June 2010 has been added

Becci Slyfield

<http://www.medsafe.govt.nz>

25/06/2010 10:35 a.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 21-25 June 2010

Additions to Medsafe's Web site from 21-25 June 2010

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Avomine, Brolene, Cefalexin Sandoz, Dimetrioise, Durogesic, Leunase, Mersyndol, Soframycin, Telnase, Vallergan and Vallergan Forte

Updated - Batrafen nail lacquer, Hepsera, Rifadin

Re-published in PDF (no changes to content) - Adenocor, Anthisan, Apidra and Apidra SoloStar, Arava, Batrafen cream and solution, Calcium Resonium, Copaxone, Cordarone X, Daonil, Epilim, Fasturtec, Flagyl, Frisium, Ikorel, ImmuCyst, Imovane, Methoblastin, Myocrisin, Neulactil, Noflam, Norpress, Nupentin, Omezol, Plaquenil, Plavix, Primacor, Proctosedyl, Resonium-A, Sculptra, Sofradex, Solian, Stemetil, Surgam, Telfast

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - DP-Quetiapine, Provive MCT-LCT, Sudomyl, Vidaza

Updated - Bridion, Hepsera, Tisseel

Re-published in PDF (no changes to content) - Adenocor, Anthisan, Apidra and Apidra SoloStar, Arava, Avomine, Batrafen cream and solution, Batrafen nail lacquer, BeneFIX, Brolene, Calcium Resonium, Chloromycetin, Copaxone, Cordarone X, Daonil, Dimetrioise, Durogesic, Elidel, Epilim, Estraderm, Exelon, Exelon patch, Fasturtec, Flagyl and Flagyl-S, Frisium, Gastrolyte, Holoxan, Ikorel, ImmuCyst, Imovane, Leunase, Loette, Meningitec, Mersyndol and Mersyndol Forte, Metronidazole, Monofeme, Myocrisin, NeisVac-C, Neulactil, Oliclinomel, Onkotrone, Paradex, Plaquenil, Plavix, Prevenar, Primacor, Proctosedyl, Recombinate, Resonium-A, Rifadin, Sabril, Sculptra, Sevoflurane, Sofradex, Soframycin, Solian, Stemetil, Suprane, Surgam, Tazocin EF, Telfast, Telnase, Uromitexan, Vallergan Forte, Xyntha

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Becci Slyfield

27/09/2010 04:26 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 20-24 September 2010

Additions to Medsafe's Web site from 20-24 September 2010

HOT TOPICS

Media Releases -

<http://www.medsafe.govt.nz/hot/media/2010/Recall6ProductsSep10.asp>

Medsafe recalls six products with undeclared prescription medicines

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Aristocort, Ativan, Atropt, Calcium Folate Ebewe, Capoten, Carboplatin Ebewe, Chlorafast, Cilicaine, Cilicaine VK, Cisplatin Ebewe, Coumadin, Diamox, Diamox, Docetaxel Ebewe, Doxorubicin Ebewe, Epirubicin Ebewe, Eutroxsig, Ferrosig, Florinef, Fludarabine Ebewe, Fungilin, Gemcitabine Ebewe injection concentrate, Gemcitabine Ebewe powder for injection, Irinotecan Ebewe, Kenacort A10, Kenacort A40, Lycinate, Megace, Methotrexate Ebewe, Myambutol, Nilstat, Nilstat, Normison, Oxaliplatin Ebewe, Pravachol, Pro-banthine, Q200 and Q300, Questran Lite, Robinul, Serenace injection solution, Serenace tablet and liquid, Urex Forte, Vinorelbine Ebewe

Updated - BeneFIX, Ciproxin IV, Ciproxin tablet, Daclin, Diflucan One capsule, Duac, Fluorouracil Ebewe, Fragmin, Hiberix, Kenacomb, Mitozantrone Ebewe, Paclitaxel Ebewe, Parnate, Pexsig, Sprycel, Sutent, Ventavis

Re-published in PDF (no changes to content) - 2% Xylocaine Dental with Adrenaline, 3% Citanest Dental with Octapressin, Agenerase capsules, Agenerase oral solution, Beclazone CFC-Free inhaler, Cardizem, Clomazol, Eloxatin, Epilim tablet and oral liquid, Ipratropium Steri-Nebs, Levothyroxine, M-Cefazolin, Noflam, Nupentin, Oraquix, Pacifen, Pacific Buspirone, Paxam, Pindol, Piram-D, Quetapel, Ridaura, Rifadin, Risperon, Sabril, Salamol CFC-Free, Somac, Sotalol, Stelazine, Stieprox, Sumagran Active, Tramedo, Trisul, Vancomycin, Ventolin inhaler aerosol metered, Verpamil, Xergic, Zovirax cold sore cream

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Risperidone

Updated - Aclasta, BeneFIX, Cilazapril-AFT, Daclin, DBL Phenytoin injection BP, Diflucan One capsule, Engerix B, Estrofem, Fragmin, Infanrix-Hexa, Infanrix-IPV, Kliogest, Kliovance, MabCampath, Mencevax ACWY, NovoRapid, OxyContin, OxyNorm, Parnate, Prostin, Pregon, Simponi, Sutent, Trisequens, Typherix, Vagifem, Voltaren D, Voltaren injection, Voltaren SR, Voltaren suppositories, Voltaren tablets, Voltfast

Re-published in PDF (no changes to content) - 2% Xylocaine Dental with Adrenaline, 3% Citanest Dental with Octapressin, Aratac, Calcium Folate, Carboplatin Ebewe, Cardizem, Cisplatin Ebewe, Docetaxel Ebewe, Doxorubicin

Ebewe, Eloxatin, Epirubicin Ebewe, Floxapen, Fluorouracil Ebewe Fludarabine
Ebewe, Gemcitabine Ebewe, Kivexa, Loxalate, MabCampath, Methotrexate Ebewe,
Mitozantrone Ebewe, Neo-Cytamen, Oraqix, Oxaliplatin Ebewe, Stelazine,
Suboxone, Temgesic, Trizivir, Ultravist, Urografin, Vergo 16, Vinorelbine Ebewe,
Ziagen solution, Ziagen tablet, Zofran Zydis

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 16 and 23 September 2010 have been added

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Becci Slyfield

[REDACTED]

<http://www.medsafe.govt.nz>

[REDACTED]

RELEASED UNDER THE OFFICIAL INFORMATION ACT

18/01/2011 04:12 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 13 December 2010 - 14 January 2011

Additions to Medsafe's Web site from 13 December 2010 - 14 January 2011

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Carbaccord, Compound Sodium Lactate (Hartmann's), DP-Omeprazole, Epiccord, Estradot, Irinoccord, Ondanaccord, Oxaliccord

Updated - Comtan, Cozaar, Renitec and Renitec M, Permax, Apidra and Apidra Solostar, Dopergin, Xarelto, Luveris, Betoptic S, Pentasa, Camptosar, Volibris, Lithicarb FC, Avaxim, Januvia, Janumet, Comvax, Lantus, Cubicin

Re-published in PDF (no changes to content) - Humalog cartridge and Humalog Mix, Humalog vial, Humulin cartridge, Humulin vial

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

Minutes of the November 2010 Medicines Classification Committee Meeting -

<http://www.medsafe.govt.nz/profs/class/mccMin2Nov2010.htm>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Arrow Rocuronium, Carbaccord, Cefazolin-AFT, Compound Sodium Lactate (Hartmann's), DP-Omeprazole, Epiccord, Eyeprost, Irinoccord, Mestane, Mucinex, Mylan, Noradrenaline, Ondanaccord, Oxaliccord, Ropivacaine-AFT, Silvasta, Solox Relief, Univent

Updated - Apo-Allopurinol, Camptosar, Catapres TTS, Cernevit, Comvax, Coumadin, Cozaar, Diclofenac Sandoz, Epilim, Estradot, Fasturtec, Feiba NF, Gastrolyte, Humira, Hysite, Ibuprofen (Ethics), Jadelle, Janumet, Januvia, Leunase, Luveris, Modecate and Modecate Concentrate, Neulastim, Neupogen, Omnipaque, Permax, Plavix, Premarin, Renitec and Renitec M, Sabril, Sevoflurane, Synermox, Tamoxifen Sandoz, Taxol, Tracrium, Volibris

Re-published in PDF (no changes to content) - 3TC oral solution, Arrow Bendrofluzaide, Arrow Tramadol, DBL Doxorubicin Hydrochloride, Pneumo 23, Tubersol

REGULATORY INFORMATION

Certified Clinical Trial Sites - <http://www.medsafe.govt.nz/regulatory/CSSites.htm>

These have been added

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 9 December 2010, 23 December 2010 and 13 January 2011 have been added

Guidelines and Codes

Guideline on the Regulation of Therapeutic Products in New Zealand
Part 11: Good Clinical Research Practice and obtaining approval for clinical trials
and new reformatted forms have been added -
<http://www.medsafe.govt.nz/regulatory/guidelines.asp#Part11>

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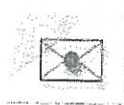
Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT



11/08/2011 03:00 p.m.

To: [Redacted]
cc: [Redacted]
bcc:

Subject: Additions to Medsafe's Web site from 27 June - 5 August 2011

Additions to Medsafe's Web site from 27 June - 5 August 2011

HOT TOPICS

Australia New Zealand Therapeutic Products Agency (ANZTPA)

Fact Sheet, dated 28 June 2011 - <http://www.medsafe.govt.nz/hot/anztpa.asp>

New Amendments to the Medicines Regulations 1984 -

<http://www.medsafe.govt.nz/hot/NewAmendmentstoMedicineRegs.asp>

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Candestar, Cholvastin, Dapsone, Daunorubicin, Femoston 2/10, Miostat intraocular, Ozole, Paracetamol + Codeine, PicoPrep, Prepkite-C, Vaclovir, ZolaCos CP

Updated - Arrow - Sumatriptan, Arrow - Venlafaxine XR, Avastin, Avigra, Botox®, Ciproxin, Cleviprex, Clozaril, Colofac, Cordarone X, Cymevene, EpiPen, EpiPen Jr, Eprex, Florinef, Fluarix, Fludara, Fludara oral, Fluox, Fragmin, Fucithalmic, Gardasil, Heparin Sodium (Pfizer), Homedin, Iressa, Isopto Carpine, Kogenate FS, Kuvan, Losec, Luvox, Lyrica, Maxalt, Maxalt Melt, Maxidex, Metopirone, MyGran, Novatrein, Ozole, Pentasa, Ponstan, Sandomigran, Serc, Silagra, Stieprox, Symmetrel, Synflorix, Temaccord, Vesicare, Vimovo, Xanax, Zanidip, ZolaCos CP, Zolft

INFORMATION FOR HEALTH PROFESSIONALS

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - AFT-Pamidronate, Ciclopirox, Co-Plavix, Desmopressin-PH&T, DisCoVisc, Duovisc, Glycoprep powder, Glycoprep-C, Hydrocortisone Butyrate Cream, Irinotecan Actavis 100, Irinotecan Actavis 40, Locacorten-Viaform, Loniten, Octalbin, Olanzapine Orodispersible tablet, Olanzapine tablet, Ondansetron-Clarix, Panvax vaccine, Provisc, Sulphacetamide Sodium Eye Drops, Terbinafine (Dr Reddy's, Travatan Z, Vigamox

Updated - Actilyse, Andriol Testocaps, Androderm, Anzatax, Aricept, Arrow - Metformin 1000, Arrow - Metformin 250, Arrow - Metformin 500, Arrow - Metformin 850, Avastin, BCG vaccine (freezedried), Biodone Forte, Botox®, Bridion, Candestar, Ceftriaxone-AFT, Cefuroxime-AFT, Cholvastin, Cisplatin Ebewe, Cleviprex, Clozaril, Colofac, Copegus, Cordarone X, Cosudex, Coversyl Plus, Cymevene, Cytarabine, Dapsone, Daunorubicin, DBL® Acetylcysteine, DBL® Atracurium Besylate Injection, DBL® Calcium Gluconate, DBL® Cefotaxime Sodium for Injection, DBL® Cefoxitin Sodium, DBL™ Epirubicin Hydrochloride, Eligard 1 Month, Eligard 3 Month, Eligard 4 Month, Eligard 6 Month, Engerix-B, Engerix-B vaccine, Epilim Intravenous, Epilim Liquid, EpiPen, Eumovate, Femoston 2/10, Florinef, Fluarix, Fludara, Fludara oral, Fludarabine Actavis 50, Fluox, Fragmin, Fucithalmic, Fuzeon, Gardasil, Gemcitabine Actavis 1000, Havrix 1440 vaccine,

Hepatitis B Immunoglobulin-VF 100IU, Hepatyrrix, Hiberix, Humira, Imovane, Infanrix-hexa, Infanrix-IPV, Isopto Carpine, Kogenate FS, Kuvan, Lithicarb FC, Logem, Lucrin, Lucrin Depot Luvox, Lyrica, Maxidex, Mencevax ACWY vaccine, Mersyndol, Metformin, Metopirone, Miostat intraocular, MyGran, Normal Immunoglobulin-VF, Novatretin, Omezol, Orenzia, Ozole, Paclitaxel Actavis, Paracetamol + Codeine, Pegasys, Pegasys RBV, PicoPrep, Pradaxa, Predonium, Predonium DS, Premarin, Premia 2.5 Continuous, Prepkite-C, Prezista, Priorix, Rocuronium, Rotarix, Sandomigran, Serc, Silagra, Simulect, Stieprox Liquid, Sutent, Symmetrel, Synflorix, Tamsulosin-Rex, Tazocin, Temaccord, Tetanus Immunoglobulin-BF, Topamax, Twinrix, Twinrix Junior, Tygacil, Typherix, Ursofalk, Varilrix, Vesicare, Xanax, Your pharmacy Paracetamol Plus, Zanidip, ZolaCos CP, Zoladex, Zoloff, Zoster Immunoglobulin-VF

Regulatory Issues

Sativex Oromucosal Spray - Requirements for Prescribers

<http://www.medsafe.govt.nz/profs/Rlss/Sativex.asp>

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 30 June, 7 July, 14 July, 21 July, 28 July, and 4 August have been added

Guidelines and Codes

Guideline on the Regulation of Therapeutic Products in New Zealand - Part 5: Labelling of medicines and related products - Edition 1.0 August 2011 -

<http://www.medsafe.govt.nz/regulatory/guidelines.asp#Part 5>

Label Statements Database - <http://www.medsafe.govt.nz/regulatory/labelling.asp>

The Label Statements Database has been updated to include Australian label statements for paracetamol and aspirin and make it clear that these are an acceptable alternative. The Australian wording for aspirin will become the mandatory form of wording in September 2012. This follows from the intention reported in the minutes of the 45th meeting of the Medicines Classification Committee held in April 2011.

The requirement for labels to include the warning that paracetamol should not be used in children under 2 years old has been removed. This warning is not required in Australia.

The statements that ibuprofen solid dose forms sold as general sale medicines should not be used in children under 6 years old or in adults over 65 years old, without doctor's advice, have been added. These were omitted in error from Edition 1 of the database, and are re-instated in this update.

The database has also been amended to clarify that the warning statements required for loperamide apply only to packs sold as general sale medicines.

The warning against using cough and cold medicines with other medicines intended to treat symptoms of the common cold has been modified to indicate that such use may be acceptable on a doctor's or pharmacist's advice.

Permitted Colourings for use in Medicines -

<http://www.medsafe.govt.nz/regulatory/Guideline/PermittedColourings.asp>

Schedule A - Declaration to accompany Consumer Medicine Information (CMI) submitted for Publication -

<http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/ScheduleAForm10.5.doc>

This form has been updated to remove the option for pdf replacement of html CMI. Only "new" or "revised" options remain.

Medical Devices / WAND -

<http://www.medsafe.govt.nz/regulatory/DevicesNew/Devices.asp>

The medical devices pages of the Medsafe website have been revised to provide information on a wide range of topics. These topics include; understanding the definition of a medical device, how to conduct basic WAND tasks, advertising of medical devices, clinical trials, in-vitro diagnostic (IVD) devices, and how to conduct a recall or corrective action. Sponsors are encouraged to use this revised information as their first point of call when they have questions about medical devices

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Becci Slyfield

[REDACTED]

<http://www.medsafe.govt.nz>

[REDACTED]



To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

14/11/2011 06:13 p.m.

Subject: Additions to Medsafe's Web site from 8 September - 14 November 2011

Additions to Medsafe's Web site from 8 September - 14 November 2011

HOT TOPICS

Media Releases

The following media releases have been issued

26 Oct 2011 - Worldwide withdrawal of Xigris (drotrecogin alfa) -
<http://www.medsafe.govt.nz/hot/media/2011/WorldwidewithdrawalofXigris.asp>

6 Oct 2011 - Medsafe recalls two products with undeclared prescription medicines -
<http://www.medsafe.govt.nz/hot/media/2011/UndeclaredPrescriptionMedicinesOct2011.asp>

30 Sept 2011 - Medsafe Warns of Dangers of Purchasing Medicines Online -
<http://www.medsafe.govt.nz/hot/media/2011/DangersOfPurchasingMedicinesOnline.asp>

15 Sept 2011 - Pradaxa (dabigatran etexilate): Questions and Answers (updated 31 October 2011) -
<http://www.medsafe.govt.nz/hot/media/2011/DabigatranQandA.asp>

INFORMATION FOR CONSUMERS

Consumer Medicine Information

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

Updated - Propecia

Quality and Safety of Medicines

Vaccine Safety -

<http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp>

This page has been added

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

The following pages have been updated

Agenda for the 46th Meeting of the Medicines Classification Committee Meeting - <http://www.medsafe.govt.nz/profs/class/agen46.htm>

Classification Process -
<http://www.medsafe.govt.nz/profs/class/classificationprocess.asp>

Current Amendment to the Classification Schedule -
<http://www.medsafe.govt.nz/profs/class/amendment.asp>

Dates and Deadlines - <http://www.medsafe.govt.nz/profs/class/dates.asp>

Recent NZ Gazette Notices Relating to Classification -
<http://www.medsafe.govt.nz/profs/class/recent.asp>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Actonel, Adenoscan, Adin Nasal Spray, Adin Tablets, Adrenaline, Aldactone, Alendronate Pfizer, Amaryl, Anaccord, Anapen, Angiomax, Apo-Alendronate, Apo-Anastrozole, Apo-Cilazapril, Apo-Cilazapril/HCTZ, Apo-Ciprofloxacin, Apo-Citalopram, Apo-Clarithromycin, Apo-Escitalopram, Apo-Gabapentin capsules, Apo-Gabapentin tablets, Apo-Imiquimod, Apo-Latanoprost, Apo-Leflunomide, Apo-Levetiracetam, Apo-Lisinopril, Apo-Olanzapine, Apo-Pantoprazole, Apo-Sildenafil, Apo-Sildenafil, Apo-Simvastatin, Apo-Topiramate, Arrow-Amlo, Arrow-Amlodipine, Arrow-Carvedilol, Arrow-Cilazapril, Arrow-Combipramol, Arrow-Gabapentin, Arrow-Ipratropium, Arrow-Isotretinoin, Arrow-Paroxetine, Arrow-Quinapril, Arrow-Ranitidine, Arrow-Ropinirole, Arrow-Salbutamol, Arrow-Simvastatin, Arrow-Stavudine, Arrow-Timolol, Atehexal, Atripla, Atorvastatin, Auro-Alendronate, Auro-Cefazolin Pfizer, Auro-Ceftriaxone, Auro-Ondansetron, Auro-Quetiapine, Ava 30, Ava 30 ED, Avage, Avodart, Blephamide, Bonviva, Bosvate, Brufen, Canesten Plus, Captohexal, Cardizem, Cefazolin Pfizer, Ceftriaxone Pfizer, Cefuroxime, Ciclofast, Ciclopoli, Clindamycin ABM, Clopidex, Clopidogrel Sandoz, Clopidogrel Winthrop, Co-Diovan, Cytraccord, Dantrium IV, DBL Zinc Chloride, DermAid, Diltahexal, Diovan, Emend IV, Enidin, Escitalopram, Finaccord, Flagyl, Fluohexal, Frusehexal, Fugere!, Galvus Met, Gammanorm, Genotropin Miniquick, Gilenya, Glimaccord, Glypressin, Humalog, Ibuprofen, Idarubicin Ebewe, Imipenem+Cilastatin RBX, Implanon NXT, Inspira, Intal Forte, Iressa, Javior, Jurnista, Juvederm Ultra XC, Juvederm Voluma XC, Kapanol, Ketek, Lamivudine Alphapharm, Letrozole Sandoz, Lopresor, Losartan HCTad, Losiva, Lumigan RC, Luveris, Lyrinel XL, m-Pergolide, Medrol, Menitorix, Menopur, Merieux, Metformin, Midaccord, Minirin Melt, Mircera, MMF-Panacea Biotech, Motetis, MST Continus, MST Mono, Mucinex, Myfortic, Nexium, Next Choice, Nifehexal, Nodia, NovoMix, Octanate, Octaplas, Olanzaccord, Ondansetron, Ondansetron, Ophthetic, Oralair, Oralcon 30, Oralcon 30 ED, Orudis SR, Oxaliplatin Actavis, Ozurdex, Panadeine, Panadeine Extra, Panafen Plus, Pantoprazole Sandoz, Panvax H1N1, Paracode Extra, Pariet, Phenytoin Sandoz, Picosalax, Poliacel, Probitor, Prolia, Promethazine Winthrop, Pronativ, Propofol, Quetiapine, Ranbaxy-Gabapentin, Ranihexal, Ranibexal, Rasilez, Relestat, Revasc, Rhesonativ, Riamet Dispersible Tablet, Riamet Tablet, Rupatal, Saizen 1.33, Saizen 8, Sildenafil Pfizer, Soliris, Somac, Sotahexal, Stelara, Tassigna, Tatig, Tisseel Fibrin Sealant VH S/D, Triasyn, Tripacel, Tritace, Truvada, Ursosan, Visacor, Vivera, Voltaren Osteo, Wilate, Xalaplus, Xalatan, Zantac tablet, Zarator, Zemaira, Zidoval, Zithromax, Zorac cream, Zorac gel, Zytram XL,

Updated - Abilify, Abraxane, Aclasta, Actrapid, Acular, Alendronate Pfizer, Amisulpride, Arabloc, Aranesp, Arava, Arrow-Cilazapril, Arrow-Citalopram, Arrow-Citalopram, Arrow-Ornidazole, Arrow-Quetiapine, Arrow-Rocuronium, Arrow-Simva, Arrow-Terbinafine, Arrow-Timolol, Auro-Ceftriaxone Pfizer, Avamys, Avodart, Botox, Butacort, Candestar, Cefazolin-AFT, Ceftriaxone Pfizer, Celebrex, Celepram, Celsentri, Certican, Champix, Children's Tixylix Night, Circadin, Citalopram, Cosmegen, Cozaar, Curam Duo, DBL Ephedrine Sulfate, DBL Leucovorin Calcium, DBL Piperacillin And Tazobactam, DBL Sodium Thiosulfate, DBL Vancomycin Hydrochloride, DBL Vinblastine Sulfate, Deca-Durabolin Orgaject, DHC Continus, Diflucan, Donezil, Donezil, Dotarem, Ecotrin, Efexor XR, Eltroxin, Enablex, Ephedrine Hydrochloride, Epilim CR, Erbitux, Estraderm, Eulexin, Exforge, Exjade, Extraneal, Famvir, Feiba NF, Flixotide, Fluanxol Depot, Fluarix, Fresofol, Frumil, Galvus, Glivec, Glivec, Gonal-F, Hepsera, Hysite, Ibiamax, Implanon NXT, Imukin, Imuprine, Integrilin, Iopidine, Isotrex, Kaletra, Kogenate FS, Lamictal,

Lamisil, Lanzol Relief, Largactil, Lasix, Leflunomide Sandoz, Leflunomide Winthrop, Lescol, Levemir, Lopresor, Loxamine, Lucentis, Lucentis, Mabthera, Mabthera, Marcain ± Adrenaline, Marcain Spinal, Mixtard, Mucinex, Multihance, Mylan Fentanyl, Neulactil, Nitroderm, Nitrolingual Aqueous, Noctamid, Norvapine, Norvir, Novoseven RT, Nozinan, Nurofen Migraine 400 Double Strength, Nurofen Migraine 400 Double Strength, Nyogel, Omezol Relief, Onbrez , Onsenal, Oruvail SR, Ovestin Cream, Ovestin Ovula Pessary, Ovestin Pessary, Ovestin Tablet, Oxynorm, Panzytrat, Penmix, Pentasa, Pepzan, Pergoveris, Persantin PL, Pharmacist's Own Pain Relief, Pharmacist's Own Pain Relief Plus, Pharmorubicin, Physioneal 40, Piportil Depot, Pizaccord, Ponstan, Postinor-1, Premia Low, Primacor, Priorix Tetra, Propecia, Protaphane, Quinapril, RA-Morph, Ranbaxy-Cefaclor, Rectogesic, Renagel, Respigen, Revlimid, Saizen 3, Saizen 8, Seroquel, Seroquel XR, Simstatin, Stelara, Stemetil, Stromectol, Sudomyl, Sustanon, Synagis, Synflorix, Synthroid, Tambacor, Tamoxifen Sandoz, Targin, Taxotere, Taxotere, Tegretol, Temaccord, Tilade, Tisseel Fibrin Sealant VH S/D, Stalevo, Tobi, Tykerb, Vergo 16, Vermox Oral Suspension, Vermox Tablet, Vidaza, Viread, Voltaren Rapid, Xalacom, Xylocaine ± Adrenaline, Zantac, Zantac Syrup, Zarontin, Zeldox IM, Zofran Injection, Zofran Tablets, Zofran Zydis, Zytram BD

Re-published in PDF (no changes to content) - Acihexal, Acupan, Advantan, Aldara, Aromasin, Arrow-Gliclazide, Arrow-Tramadol, Benpen, Calcium Disodium Versenate, Cytarabine, Daivobet, Doloproct, Duromine, Durotram XR, Enbrel, Fluorouracil Pfizer, Fucidin, Infanrix, Infanrix Hib, Infanrix IPV-Hib, Infanrix-penta, Intanza, Macugen, Meningitec, Norflex, Nuelin, Nuelin-SR, Ocuflox, One Alpha, Paediacel, Prevenar, Prevenar 13, Rapamune, Reminyl, Skinoren, Solox, Stesolid Rectal Tubes, Streptase, Tambacor, Tramal, Ultraproct, Vaxigrip Junior

M² Medicines Monitoring

<http://www.medsafe.govt.nz/profs/M2MedicinesMonitoring.asp>

This page has been updated

Regulatory Issues

Restrictions on the Prescribing, Supply and Administration of Medicines under the Medicines Act 1981 & the Misuse of Drugs Regulations 1977 -

<http://www.medsafe.govt.nz/profs/RIss/restrict.asp>

This page has been updated

REGULATORY INFORMATION

Forms - <http://www.medsafe.govt.nz/regulatory/forms.asp>

- The following forms have been updated
- CMN Form A
- CMN Form B
- Labelling Declaration Form
- NMA Form
- Proprietary Ingredient Form

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notices for 11 August, 18 August, 25 August, 1 September, 8 September have been added

Guidelines & Codes

Guideline on the Regulation of Therapeutic Products in New Zealand -

<http://www.medsafe.govt.nz/regulatory/guidelines.asp>

Part 5: Labelling of medicines and related product

Update to the Label Statements Database - Edition 1.4, October 2011

Pseudoephedrine has been removed from the listing in the group Cough and cold medicines, as it is now a scheduled prescription medicine and no longer available for use in OTC cough and cold medicines.

Phenylephrine has been added to the group Cough and cold medicines, as companies are re-formulating their products to use this in place of pseudoephedrine.

The warning statement required for topical products, including corticosteroids for topical use, has been revised to "Caution: Contains [names of any preservatives or allergens]" , as the warning applies only if the product contains preservatives or allergens.

The condition for requiring the warning statements for Salicylates has been changed to say "Salicylates, other than aspirin, for oral use". Aspirin has its own set of required warning statements.

The statement "Consult a doctor before use if you are at risk of bleeding problems." was incorrectly included for proton pump inhibitors and has been removed.'

Part 7: Advertising of therapeutic products

This has been added

Part 10: Requirements for information for prescribers and consumers

To include updates relating to changes in the Medicines Regulations

New Zealand Regulatory Guidelines for Medicines

Volume 1: Guidance notes for applicants for consent to distribute new and changed medicines and related products

Part C - Addition of requirements for priority assessment status, minor editorial changes. Remove section on classification and redirect to "Classification" section of website

Parts E, F and G - Deleted as refers to superseded processes

Guideline -

<http://www.medsafe.govt.nz/regulatory/Guideline/NZRGM%20Volume%201.asp>

Summary of Changes -

<http://www.medsafe.govt.nz/regulatory/Guideline/summaryofchanges.asp>

Medicines Assessment Advisory Committee -

<http://www.medsafe.govt.nz/regulatory/MAACcontents.asp>

These pages have been updated

Product/Application Search

Evaluation Timeframes -

<http://www.medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp>

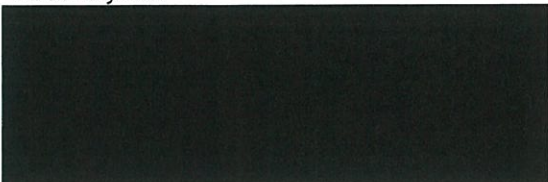
This page has been updated

Weight Management/Weight Loss Products -

<http://www.medsafe.govt.nz/regulatory/Weight/weightcontents.asp>

This page has been updated

Becci Slyfield



<http://www.medsafe.govt.nz>



RELEASED UNDER THE
OFFICIAL INFORMATION ACT

25/02/2013 04:43 p.m.

To:
cc:
bcc:

Subject: Additions to Medsafe's Web site from 4-22 February 2013

Additions to Medsafe's Web site from 4-22 February 2013

INFORMATION FOR CONSUMERS

Consumer Medicine Information -

<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

New - Arrow-Quinapril tablet, Stieprox liquid shampoo

Updated - Androderm patch, Anten capsule, Arrow-Amitriptyline tablet, Arrow-Diazepam tablet, Betaloc CR tablet, Betoptic eye drops, Betoptic S eye drops, Bezalip and Bezalip Retard tablet, Bridion solution for injection, Cetrotide powder for injection, Cialis tablet, Cordarone X tablet and injection solution, Disipal tablet, Ebixa tablet lactose free, Ebixa tablet with lactose, Epilim EC and Liquid and 100 Crushable and tablet, Epilim intravenous injection, Humalog solution for injection, Humalog solution for injection cartridge and Humalog MIX25 and MIX50 suspension for injection, Humalog solution for injection pre-filled pen and Humalog MIX25 and MIX50 pre-filled pen, Humulin solution for injection cartridge, Humulin solution for injection vial, Imukin injection solution, Mabthera infusion concentrate, Mencevax ACWY vaccine, Olanzine + Olanzine-D tablet, Pacifen tablet, Premarin tablet, Propecia tablet, Proscar tablet, Quetapel tablet, Risperon oral solution, Rizamelt Orodispersible tablet, Simdax injection, Simponi solution for injection and SmartJect, Staphlex capsule, Sublimaze solution for injection, Tarceva tablet, Tasmart tablet, TMR tablet, Tykerb tablet, Ventavis solution for inhalation, Wartec cream, Zoladex 10.8 implant, Zoladex 3.6 implant

INFORMATION FOR HEALTH PROFESSIONALS

Classification of Medicines

Agenda for the 40th Meeting of the Medicines Classification Committee meeting has been added - <http://www.medsafe.govt.nz/profs/class/agen49.htm>

Dates and Deadlines page has been updated -

<http://www.medsafe.govt.nz/profs/class/dates.asp>

Gazette Notice for 7 February 2013 relating to classification has been added -

<http://www.medsafe.govt.nz/profs/class/recent.asp>

Datasheets - <http://www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp>

New - Alcaine eye drops, Eylea injection solution, Isopto Carpine eye drops, Methotrexate Sandoz injection with diluent, Polyvisc eye ointment, Tobrex eye drops, Victrelis Pegatron Combination Therapy

Updated - Alimta vial, Amirol tablet, Amitrip tablet, Androderm patch, Anten capsule, Apo-Moclobemide FCT, Apo-Terbinafine tablet, Arrow Amitriptyline tablet, Arrow-Diazepam tablet, Aurorix tablet, Avigra tablet, Betnovate lotion, Betnovate-C cream and ointment, Betoptic eye drops solution and Betoptic S eye drops suspension, Bricanyl turbuhaler, Bridion solution for injection, Budenocort powder for inhalation, Cancidas powder for injection, Carafate tablet, CeeNU capsule, Cetrotide powder for injection, Cisplatin ABM injection solution, Clozaril tablet, Codeine

Phosphate tablet, Diane-35 ED tablet, Disipal tablet, Dopress capsule, Droleptan solution for injection, Dynastat powder for injection, Ebixa tablet lactose free, Ebixa tablet with lactose, Elaprase infusion, Eumovate topical cream, Fentanyl solution for injection, Haldol and Haldol Concentrate injection, Humalog solution for injection, Humalog solution for injection cartridge/KwikPen and solution for injection and Humalog MIX25 and MIX50 suspension and pen suspension for injection, Humulin solution for injection cartridge and vial, Hypam tablet, Invanz powder for injection, Largactil tablet and injection and solution, Leflunomide Sandoz tablet, Lucrin solution for injection, Lucrin suspension for injection, Ludiomil tablet, Luvox tablet, Mabthera infusion concentrate, Magnevist solution for injection, Maxolon tablet, Mencevax ACWY vaccine, Muphoran injection solution, Naropin with Fentanyl infusion solution, Neulactil tablet, Nitrados tablet, Norpress tablet, Nozinar tablet and injection and solution, Olanzine + Olanzine-D tablet, Oxytrol patch, Pacifen tablet, Piportil depot injection solution, Premarin tablet, Propecia tablet, Proscar tablet, Quetapel tablet, Risperdal Consta powder for injection, Risperdal tablet and oral solution and orodispersible tablet, Rizamelt orodispersible tablet, Singulair tablet, Solian table and oral solution, Sporanox capsule, Sporanox solution, Staphlex capsule, Stelazine tablet and liquid oral and spansules, Sublimaze solution for injection, Tacrolimus Sandoz, Tamiflu capsule, Tarceva tablet, Tasmart tablet, Tegretol tablet and CR and syrup, Terbinafine-DRLA tablet, TMP tablet, Tofranil tablet, Tykerb tablet, Vimovo tablet, Zarzio solution for injection

Medicines Monitoring

Outcomes of Medicines Previously on M²

<http://www.medsafe.govt.nz/profs/M2MedicinesMonitoringOutcomes.asp>

The following have been added

- Lithium and Diabetes Mellitus Type 2
- Proton Pump Inhibitors and Hypocalcaemia

REGULATORY INFORMATION

Gazette Notices - <http://www.medsafe.govt.nz/Regulatory/gazette.asp>

Gazette Notice for 7, 14 and 21 February 2013 have been added

Guidelines & Codes -

<http://www.medsafe.govt.nz/regulatory/Guideline/PolicyForChangingRegistrationSituation.asp>

Medsafe's policy for Changing Registration Situation has been added -

Introductory Regulatory Guidance -

<http://www.medsafe.govt.nz/regulatory/RegulatoryGuidance/Introduction.asp>

This new section has been added

Product/Application Search -

<http://www.medsafe.govt.nz/regulatory/Performance2012.asp>

Performance against evaluation timeframes 2012 has been added

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<http://www.medsafe.govt.nz>

[REDACTED]

RELEASED UNDER THE
OFFICIAL INFORMATION ACT



06/05/2014 05:09 p.m.

To:
cc:
bcc:



Subject: Additions and Updates to Medsafe's Website from 28 April - 2 May 2014

Additions and Updates to Medsafe's Website from 28 April – 2 May 2014

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

ABOUT MEDSAFE

Vacancies

Advisor/Senior Advisor (Science), Pre-Market Medicines Assessment

CONSULTATIONS

Outcome of Consultation Topics

Outcome of consultation on the planned changes to the prescribing restrictions for clozapine

CONSUMER MEDICINE INFORMATION

New - Coldrex Hot Remedy Cold & Flu Plus with Decongestant Hot, Difucid tablet

Updated - Atacand tablet, Celapram tablet, FML eye drops solution, HBvaxPRO vaccine solution for injection, Lamivudine Alphapharm tablet, Lanzol Relief capsule, Omezol Relief capsule, Plaquenil tablet, Sinemet CR tablet, Sinemet tablet, Sutent capsule, Vedafilet tablet, Zarzio solution for injection

DATA SHEETS

New - Difucid tablet

Updated - Aclasta solution for infusion, Amyl Nitrite inhalant, Apo-Bromocriptine capsule, Apo-Bromocriptine tablet, Apo-Prazosin tablet, Arrow – Norfloxacin tablet, Celapram tablet, Cilicaine VK capsule, DBL Cefotaxime Sodium for injection, Epilim EC tablet and liquid solution and intravenous injection solution, Finasteride tablet, HBvaxPRO vaccine solution for injection, Intelence tablet, Janumet tablet, Lamivudine Alphapharm tablet, Lanzol Relief capsule, Mersyndol tablet, Mycobutin capsule, Naropin with Fentanyl infusion, Nexium tablet, Plaquenil tablet, Polyvisc eye ointment, Reyataz capsule, Ropin tablet, Sinemet CR tablet (new formulation), Sinemet CR tablet (old formulation), Sinemet tablet (new formulation), Sinemet tablet (old formulation), Sutent capsule, Tobrex eye drops solution, Vedafilet tablet, Xgeva solution for injection, Ziagen oral solution, Ziagen tablet

MEDICINES

Biosimilars

Medsafe's Position on Biosimilars has been updated

Restrictions on the Supply, Prescribing or Administration of Medicines under the

Medicines Act 1981 and Misuse of Drugs Regulations 1977
Clozapine has been updated

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[REDACTED]

<http://www.medsafe.govt.nz>

[REDACTED]

RELEASED UNDER THE
OFFICIAL INFORMATION ACT



13/05/2014 04:20 p.m.

To:
cc:
bcc:

Subject: Additions and Updates to Medsafe's Website from 5 - 12 May 2014

Additions and Updates to Medsafe's Website from 5 - 12 May 2014

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

COMMITTEES

Medicines Assessment Advisory Committee

Vacancies

The application date has been extended to 13 June 2014

CONSUMER MEDICINE INFORMATION

New - Coldrex PE Phenylephrine Congestion Clear, Montelukast Actavis tablet, Ovidrel solution for injection (pen-filled pen), Reutenox tablet,

Updated - Antabuse tablet, Anten capsule, Apo-Ropinirole tablet, Asamax suppository, Asamax tablet, Beta Scalp Application, scalp lotion, Dopress capsule and tablet, Epilim intravenous, Epilim syrup and tablet and oral solution, Fluox capsule and tablet, Kaletra solution and tablet, Loette tablet, Lucentis solution for injection, Madopar tablet, Mirena intrauterine contraceptive device, Monofeme tablet, Neo-Mercazole tablet, Nexavar tablet, Norvir solution and tablet, Protos granules for oral suspension, Quetapel tablet, Rizamelt tablet, Stesolid rectal tubes, Zolofit tablet, Zypine tablet

DATA SHEETS

New - DBL Magnesium Sulfate solution for injection, Juvederm Hydrate injection solution, Montelukast Actavis tablet, Ovidrel solution for injection (pen-filled pen), Plasmalyte infusion solution, Reutenox tablet

Updated - Anten capsule, Apo-Ropinirole tablet, Aropax tablet, Arrow-Fluoxetine capsule and tablet, Arrow-Sumatriptan injection solution, Asamax 500 suppository, Asamax 500 tablet, Beta Scalp Application, scalp lotion, Calcium Chloride (AFT) injection solution, Celapram tablet, Diamide capsule, Diprosone OV topical cream and ointment, Diprosone topical cream and ointment, Donepezil tablet, Dopress capsule and tablet, Doxorubicin Ebewe concentrate for injection, Forthane volatile liquid for inhalation, Havrix 1440 and Havrix Junior injection suspension, Imigran injection, Imigran tablet, Inlyta tablet, Kaletra solution and tablet, Kliogest tablet, Loette tablet, Madopar tablet and capsule, Maxalt and Maxalt Melt Wafer, Maxalt tablet, Maxidex eye drops suspension, Mencevax ACWY vaccine injection, Mirena intrauterine contraceptive device, Monofeme tablet, Naramig tablet, Nexavar tablet, Norvir solution and tablet, Oruvail SR capsule, Protos granules for oral suspension, Quetapel tablet, Sevorane volatile liquid for inhalation, Synagis injection, Trisequens tablet, Tykerb tablet, Typerix injection suspension, Voltaren Ophtha eye drops

solution

MEDICINES

Forms and Templates

The following forms have been updated as part of the annual review. Only minor changes have been made to improve clarification:

- Declaration to accompany a CMI submitted for publication (*Microsoft Word document 46KB*)
- Drug Master File / Plasma Master File / Certificate of Suitability (*Microsoft Word 48KB*)

SAFETY INFORMATION

Trans-Tasman Early Warning System

Provide MCT - LCT 1% Emulsion for Injection (10mg/mL) and Provide 1% Emulsion for Injection (10mg/mL) - investigation of infection in Australia

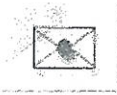
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Becci Slyfield

[REDACTED]

<http://www.medsafe.govt.nz>

[REDACTED]



Sent by: Becci Slyfield/MOH

26/03/2015 04:37 p.m.

To: Becci Slyfield/MOH@MOH,
cc:
bcc:

Subject: Additions to the Medsafe Website from 16 - 23 March 2015

Additions to the Medsafe Website from 16 - 23 March 2015

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION

New – Silvasta tablet

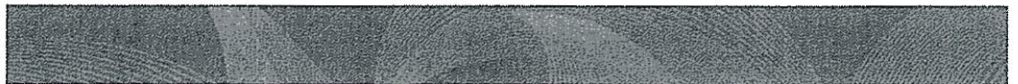
Updated – Epilim intravenous, Epilim syrup and tablet and Modified release tablet and oral solution, Rulide D tablet, Zostavax Zoster virus vaccine

DATA SHEETS

Updated – Aratac tablet, Avastin injection concentrated, Bactroban topical ointment, Epilim syrup and tablet and Modified release tablet and oral solution and intravenous injection solution, Epilim tablet and oral solution and solution for injection and syrup, Kivexa tablet, Neulastim injection solution, Neupogen injection solution, Omezol Relief capsule, Phenergan tablet and elixir, Picosalax powder, Plavix tablet, Proctosedyl ointment and suppository, Rulide D tablet, Serenace liquid oral solution, Tivicay tablet, Xeomin injection powder, Zostavax Zoster virus vaccine

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Becci Slyfield | Clinical Trial Co-ordinator/Web Publishing | Clinical Risk Management | Medsafe | Ministry of Health | [REDACTED] www.medsafe.govt.nz





07/04/2015 02:32 p.m.

To:
CC:
bcc:

Subject: Additions to the Medsafe Website from 30 March - 7 April 2015

Additions to the Medsafe Website from 30 March – 7 April 2015

This email is to inform you of recent additions and updates the Medsafe website. This list is in alphabetical order.

CONSULTATIONS

Current Consultation Topics

Guideline on the Regulation of Therapeutic Products in New Zealand. Part 8: Pharmacovigilance

CONSUMER MEDICINE INFORMATION

New - Fluquadri and Fluquadri Junior suspension for injection, Jakavi tablet

Updated – Bactroban ointment, Dermal cream and ointment, Efexor-XR capsule, Fucithalmic eye drops, Imuprine tablet, Logem tablet, Maxidex eye drops, Stivarga tablet, Tafinlar capsule, Ultiva powder, Ursosan capsule

DATA SHEETS

New – Jakavi tablet, PipTaz-AFT injection powder

Updated – Beconase Allergy & Hayfever 12 hour nasal spray, Celapram tablet, Dermal topical cream and ointment, Epilim EC tablet and oral solution and solution for injection and modified release tablet and syrup, Fluquadri and Fluquadri Junior suspension for injection, Forxiga tablet, Imuprine tablet, Logem tablet, Maxidex eye drops, Stivarga tablet, Tafinlar capsule, Tisseel topical solution, Ursosan capsule, Victrellis capsule, Zelboraf tablet, Zeldox capsule, Zeldox IM powder for injection

SAFETY INFORMATION

Medsafe surgical mesh implant events report updated to April 2015

Monitoring Communication

Guaifenesin (guaiphenesin) and possible risk of tinnitus added to the medicines monitoring scheme

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07/10/2015 03:03 p.m.

To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

Subject: Additions to the Medsafe Website from 28 September - 2 October 2015

Additions to the Medsafe Website from 28 September – 2 October 2015

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

ABOUT MEDSAFE

What is Medsafe?

This page has been updated to reflect changes in the organisational structure of Medsafe

COMMITTEES

Medicines Adverse Reactions Committee

Minutes of the 163rd Medicines Adverse Reactions Committee meeting - 10 September 2015

CONSUMER MEDICINE INFORMATION

New - Vimizim concentrate for infusion

Updated - Implanon NXT subcutaneous implant, Sandomigran tablet, Xalkori capsule

DATA SHEETS

New - Flumazenil injection solution, Vimizim concentrate for infusion, ViruPOS eye ointment

Updated - Abilify tablet, Atacand tablet, Avonex injection with diluent and solution with diluent and Avonex Pen solution for injection, Concerta tablet, Fampyra tablet, Frumil tablet, Glaumox powder for injection, Implanon NXT subcutaneous implant, Perfalgan solution for injection, Perjeta injection concentrate, Remicade powder for infusion concentrate, Sandomigran tablet, Symbicort powder for inhalation, Tecfidera capsule, Tramal oral drops and solution for injection and capsules and SR modified release tablet, Tysabri solution for infusion, Xalkori capsule

SAFETY INFORMATION

Alert Communication

Use of sodium valproate (Epilim) in pregnancy

Surgical Mesh Implants

Medsafe surgical mesh implant events report - October 2015 (PDF 758 KB, 21 pages)

Trans-Tasman Early Warning System

[Audit of the first 12 months of the early warning system \(PDF, 350KB, 14 pages \)](#)

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15/12/2015 11:45 a.m.

To:
cc:
bcc:



Subject: Additions to the Medsafe Website from 7-11 December 2015

Additions to the Medsafe Website from 7-11 December 2015

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION

New – Apo-Riluzole (riluzole) tablet, Desferal (deferoxamine) powder for injection, Sertraline Actavis (sertraline) tablet

Updated – Coldrex PE (paracetamol; phenylephrine) Phenylephrine Congestion Clear, Coldrex PE (paracetamol; phenylephrine) Phenylephrine Sinus, Eumovate (clobetasone) topical cream (restricted), Gadovist (gadobutrol) solution for injection, Omezol Relief (omeprazole) capsule, Vfend (voriconazole) tablet and powder for injection and powder for oral suspension, Zyprexa Relprevv (olanzapine) powder for injection

DATA SHEETS

New - Apo-Riluzole (riluzole) tablet, Desferal (deferoxamine) powder for injection, Sertraline Actavis (sertraline) tablet

Updated – Acilin (sulindac) tablet, Ativan (lorazepam) tablet, Dapsone (dapsone) tablet, Epilin (valproic acid) tablet and intravenous solution for injection and liquid oral solution and syrup, Flixotide (fluticasone) Aerosol inhaler and Flixotide Junior (fluticasone) aerosol inhaler, Flixotide Accuhaler (fluticasone) powder for inhalation, Gadovist (gadobutrol) solution for injection, Isoptin (verapamil) tablet, Isoptin (verapamil) solution for injection, Nardil (phenelzine) tablet, Nurofen Plus (codeine phosphate hemihydrate and ibuprofen) tablet, Omezol Relief (omeprazole) capsule, Remicade (infliximab) powder for infusion concentrate, Seretide Accuhaler (fluticasone; salmeterol) powder for inhalation, Syntocinon (oxytocin) solution for injection

PUBLICATIONS

Prescriber Update

Prescriber Update Vol. 36 No. 4 - December 2015 has been added

SAFETY

Alerts

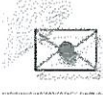
Dear Healthcare Professional Letters

Tarceva (PDF 91 KB, 2 pages) - Indication restricted to EGFR-activating mutations only

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18/04/2016 04:11 p.m.

To:
cc:
bcc:



Subject: Additions to the Medsafe Website from 11-15 April 2016

Additions to the Medsafe Website from 11-15 April 2016

This email is to inform you of recent additions and updates to the Medsafe website. This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION		
New		
Tradename	Active ingredient(s)	Dose form
Maxiclear Hayfever & Sinus Relief	loratadine; phenylephrine	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Tamiflu	oseltamivir	capsule
Avonex	interferon beta-1a	injection
Zeffix	lamivudine	oral solution
Varilrix vaccine	varicella vaccine	injection
Clindamycin ABM	clindamycin	capsule
Haldol	haloperidol	injection
Haldol concentrate	haloperidol	injection
Voltaren	diclofenac	injection
Voltaren	diclofenac	suppository
Voltaren	diclofenac	tablet
Voltaren SR	diclofenac	tablet
Voltaren D	diclofenac	tablet
Tamiflu	oseltamivir	oral suspension
Aratac	amiodarone	tablet
Infanrix IPV	diphtheria vaccine; pertussis vaccine; poliomyelitis vaccine; tetanus vaccine	injection
Gadovist	gadobutrol	injection
Revolade	eltrombopag	tablet
Saizen 3	somatropin	injection
Saizen 8	somatropin	injection

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose form
Levomepromazine Hydrochloride (Wockhardt)	levomepromazine hydrochloride	injection
Sodium Valproate	sodium valproate	injection
Zoledronic Acid	zoledronic acid	infusion
Cardioplegia Solution A	calcium chloride; magnesium chloride; potassium chloride; sodium chloride	solution
Etoposide (Rex Medical)	etoposide	injection
Updated		
Tradename	Active ingredient(s)	Dose form
Tobradex	tobramycin; dexamethasone	eye drops
Prevenar 13	pneumococcal polysaccharide conjugate vaccine	injection
Tamiflu	oseltamivir	capsules oral suspension
Synthroid	levothyroxine sodium	tablet
Avonex	interferon beta-1a	injection
Colofac	mebeverine hydrochloride	tablet
Clindamycin ABM	clindamycin hydrochloride	capsule
Ikorel	nicorandil	tablet
Caelyx	pegylated liposomal doxorubicin hydrochloride	infusion
Varilrix vaccine	varicella vaccine	injection
Haldol	haloperidol	injection
Haldol concentrate	haloperidol	injection
Voltaren	diclofenac	injection
Voltaren	diclofenac	suppository
Voltaren	diclofenac	tablet
Voltaren SR	diclofenac	tablet
Voltaren D	diclofenac	tablet
Zoloft	sertraline	tablet
Verorab	rabies vaccine	injection
Imigran	sumatriptan	injection
Imigran	sumatriptan	tablet
Revolade	eltrombopag	tablet
Saizen 3	somatropin	injection
Saizen 8	somatropin	injection
Gadovist	gadobutrol	injection
Deleted		

Tradename	Active ingredient(s)	Dose form
Gelafusal	succinic anhydride gelatin	infusion

COMMITTEES

Medicines Classification Committee

Comments on agenda items for the 55th Medicine Classification Committee Meeting

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03/08/2016 04:07 p.m.

To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

Subject: Additions to the Medsafe Website from 25 July-2 August 2016

Additions to the Medsafe Website from 25 July-2 August 2016

This email is to inform you of recent additions and updates to the Medsafe website.
This list is in alphabetical order.

CONSUMER MEDICINE INFORMATION		
New		
Tradename	Active ingredient(s)	Dose form
Gardasil 9	Human Papillomavirus 9-valent Vaccine Recombinant	injection
Ozurdex	dexamethasone	
Paracetamol Kabi	paracetamol	injection
Proveblue	methylene blue (as trihydrate)	injection
Updated		
Tradename	Active ingredient(s)	Dose form
Afinitor	everolimus	tablet
Antabuse	disulfiram	tablet
Arrow Amitriptyline	amitriptyline hydrochloride	tablet
Arrow-Quinapril	quinapril	tablet
Cerazette	desogestrel	tablet
Dilantin	phenytoin phenytoin sodium	capsule tablet oral suspension
Glucose 5% Freeflex	glucose monohydrate	infusion
Kalydeco	ivacaftor	tablet
Tilcotil	Tenoxicam	tablet
Varivax	varicella virus vaccine live (Oka/Merck)	injection
Zetop	cetirizine hydrochloride	tablet
Ziagen	abacavir sulphate	oral solution

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose form

Gardasil 9	Human Papillomavirus 9-valent Vaccine, Recombinant	injection
Paracetamol Kabi	paracetamol	injection
Proveblue	methylene blue (as trihydrate)	injection
Tobramycin Mylan	Tobramycin	injection
Zista	Cetirizine hydrochloride	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Afinitor	everolimus	tablet
BICNU	carmustine	injection
Cerazette	desogestrel	tablet
Cervidil	dinoprostone (prostaglandin e2)	vaginal pessary
Cubucin	daptomycin	infusion
Dilantin	phenytoin phenytoin sodium	capsule tablet oral suspension
Epilim	Sodium valproate	tablet injection liquid oral solution syrup
Erivedge	vismodegib	capsule
Extraneal	icodextrin	solution
Glucose 5% Freeflex	glucose monohydrate	infusion
Kalydeco	ivacaftor	tablet
Logem	lamotrigine	tablet
Premarin	conjugated estrogens	tablet
Premia	conjugated estrogens and medroxyprogesterone acetate	tablet
Tamiflu	Oseltamivir	oral suspension capsule
Varivax	varicella virus vaccine live (Oka/Merck)	injection
VPRIV	velaglucerase alfa	infusion
Zetop	cetirizine hydrochloride	tablet
Ziagen	abacavir sulphate	oral solution

COMMITTEES

Medicines Adverse Reactions Committee

Minutes of the 166th Medicines Adverse Reactions Committee Meeting - 29 June 2016

DIETARY SUPPLEMENTS

Regulation of Dietary Supplements

Application Form for an Export Certificate for Dietary Supplements (PDF 101kb, 2 pages) has been updated.

PUBLICATIONS

Prescriber Update

Prescriber Update Reader Satisfaction Survey July 2016 - Survey Outcome Report (PDF 4024 KB, 17 pages)

SAFETY

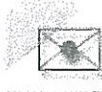
Alerts

Early Warning System Alert Communications

Quickie Q7 Wheelchair (Model ER14) manufactured between 1 September 2009 & 27 November 2013. (Backrest Bracket Damage)

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09/01/2017 05:30 p.m.

To: [Redacted]
cc: [Redacted]
bcc: [Redacted]

Subject: Additions to the Medsafe Website from 5 December 2016 - 6 January 2017

Additions to the Medsafe Website from 5 December 2016 - 6 January 2017

This email is to inform you of recent additions and updates to the Medsafe website.

COMMITTEES

Medicines Adverse Reactions Committee

Medicines Adverse Reactions Committee - Minutes for the 168th Meeting - 1 December 2016

Medicines Classification Committee

Medicines Classification Committee - Recent Gazette Notices

Medicines Classification Committee - Dates and Deadlines

MEDICAL DEVICES

Update: Implementation of Government Response to Report of the Health Committee on Petition 2011/102

Reporting Adverse Events Associated With Medical Devices

PUBLICATIONS

Information for Women with Breast Implants

Prescriber Update

Vol. 37 No. 4 - December 2016

Answers to the Prescriber Update Quiz - December 2016

SAFETY INFORMATION

Update to Monitoring Communication

EasyCheck hCG Urine Pregnancy Test Cassette – Invalid (Negative) and Inconclusive Results

Alert Communication

Consumer Level Recall – Pivot, Pivot Hygiene, Pivot Hammock and Tony Pringle clip style sling used for patient hoists

CONSUMER MEDICINE INFORMATION

New		
Tradename	Active ingredient(s)	Dose form
Copegus	ribavirin	tablet
Finasteride (Pharmacare) 1mg	finasteride	tablet
Finasteride (Pharmacare) 5mg	finasteride	tablet
Noradrenaline BNM	noradrenaline	injection

One Alpha	alfacalcidol	capsule oral drops
Rheumon	etofenamate	topical gel
Sativex	cannabidiol; tetrahydrocannabinol	oral spray
Zepatier	elbasvir; grazoprevir	tablet
Updated		
Tradename	Active ingredient(s)	Dose form
Beclazone	beclometasone	cfc-free in inhaler
Benzac AC	benzoyl peroxide	topical gel
Brilinta	ticagrelor	tablet
Cardizem and Cardizem CD	diltiazem	capsule tablet
Clobex	clobetasol	shampoo
Depo-Provera	medroxyprogesterone	injection
Enbrel	etanercept	injection
Epiduo	adapalene; benzoyl peroxide	gel
Epilim	valproic acid	injection
Epilim and Epilim EC	valproic acid	tablet liquid solu syrup
Erivedge	vismodegib	capsule
Estradol	estradiol	transderm
Eviplera	emtricitabine; rilpivirine; tenofovir	tablet
FluQuadri and FluQuadri Junior	influenza vaccine polyvalent	injection
Imbruvica	ibrutinib	capsule
Influvac	influenza vaccine polyvalent	injection
Klacid	clarithromycin	tablet oral suspe injection modified r
Konakion MM and Konakion MM Paediatric	phytomenadione	injection
Marvelon 28	desogestrel; ethinylestradiol	tablet
Mercilon 28	desogestrel; ethinylestradiol	tablet
Metvix	methyl aminolevulinate	cream
MMR II Vaccine	measles vaccine; mumps vaccine; rubella vaccine	injection

NuvaRing	ethinylestradiol; etonogestrel	vaginal rin
Polaramine	dexchlorpheniramine	tablet
Postinor-1	levonorgestrel	tablet
Provera and Provera HD	medroxyprogesterone	tablet
Revlimid	lenalidomide	capsule
Rifadin	rifampicin	capsule
Sutent	sunitinib	capsule
Thalomid	thalidomide	capsule
Tramadol Hydrochloride	tramadol	capsule
Vaxigrip	influenza vaccine polyvalent	injection
Vttack	voriconazole	tablet

DATA SHEETS

New		
Tradename	Active ingredient(s)	Dose fo
Allmercap	mercaptopurine	oral sus
Apo-Paroxetine	paroxetine	tablet
Finasteride (Pharmacare) 1mg	finasteride	tablet
Finasteride (Pharmacare) 5mg	finasteride	tablet
Noradrenaline BNM	noradrenaline	injectior
One Alpha	alfacalcidol	capsule
		oral dro
Rheumon	etofenamate	topical g
Zepatler	elbasvir; grazoprevir	tablet
Updated		
Tradename	Active ingredient(s)	Dose fo
Abilify	aripiprazole	tablet
Angiomax	bivalirudin	injectior
Angiomax	bivalirudin	injectior
Beclazone	beclometasone	cfc-free
		inhaler
Brilinta	ticagrelor	tablet
Cafergot	caffeine; ergotamine	tablet
Cardizem	diltiazem	tablet
Cardizem CD	diltiazem	capsule
Concerta	methylphenidate	tablet
Creon	pancreatin	capsule
Depo-Provera	medroxyprogesterone	injectior
Depo-Testosterone	testosterone	injectior
Dexamethasone	dexamethasone	injectior
Effient	prasugrel	tablet

Enbrel	etanercept	injectior
Epilim and Epilim EC	valproic acid	tablet
		injectior
		oral soli
		syrup
EpiPen and EpiPen Junior	adrenaline	injectior
Erivedge	vismodegib	capsule
Esbriet	pirfenidone	capsule
Estradot	estradiol	transde
Eviplera	emtricitabine; rilpivirine; tenofovir	tablet
FluQuadri and FluQuadri Junior	influenza vaccine polyvalent	injectior
Gonal-F	follitropin	injectior
Imbruvica	ibrutinib	capsule
Influvac	influenza vaccine polyvalent	injectior
Isoptin	verapamil	injectior
Klacid	clarithromycin	tablet
		oral sus
		injectior
		modifie
Konakion MM and Konakion MM Paediatric	phytomenadione	injectior
Marvelon 28	desogestrel; ethinylestradiol	tablet
MMR II Vaccine	measles vaccine; mumps vaccine; rubella vaccine	injectior
Nauzene	cyclizine	tablet
Noxafil	posaconazole	tablet
NuvaRing	ethinylestradiol; etonogestrel	vaginal
Otezla	apremilast	tablet
Pentacarinat	pentamidine	injectior
Polaramine	dexchlorpheniramine	tablet
Postinor-1	levonorgestrel	tablet
Provera and Provera HD	medroxyprogesterone acetate	tablet
Reminyl	galantamine	capsule
Risperdal and Risperdal Quicklet	risperidone	tablet
Rytmonorm	propafenone	tablet
Simponi	golimumab	injectior
Strattera	atomoxetine	capsule
Suboxone	buprenorphine; naloxone	tablet
Sutent	sunitinib	capsule

Temgesic	buprenorphine	injectior
Thalomid	thalidomide	capsule
Tramadol Hydrochloride	tramadol	capsule
Vaxigrip	influenza vaccine polyvalent	injectior
Vttack	voriconazole	tablet
Zerbaxa	ceftolozane; tazobactam	injectior
Zyprexa	olanzapine	injectior
Zyprexa and Zyprexa Zydis	olanzapine	tablet
		wafer
Zyprexa Relprevv	olanzapine	injectior

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