22 May 2025

Zyprexa IM (olanzapine) 10mg powder for injection: Temporary supply of overseas product

This information is being sent in agreement with Medsafe.

Dear Healthcare Professional,

Due to a temporary supply shortage of Zyprexa IM (olanzapine), Pharmaco (NZ) Ltd will be supplying one batch of an overseas pack with the following details:
Batch number: B10/3
Expiry date: 11/2026

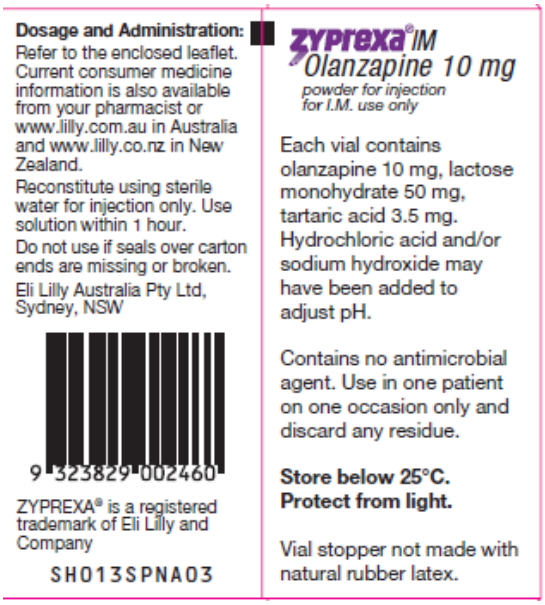
This overseas labelled product has the same formulation, volume, dosage form and manufacturer as the NZ product.

Please find a comparison of the proposed overseas pack with the NZ product labelling below:

Current NZ packaging	Overseas packaging
Carton main panel *Slight differences in the wording of information and name of product*	
	

Side panels of carton

Tighter storage conditions mentioned on the alternative pack



Dosage and Administration:
Refer to the enclosed leaflet. Current consumer medicine information is also available from your pharmacist or www.lilly.com.au in Australia and www.lilly.co.nz in New Zealand.
Reconstitute using sterile water for injection only. Use solution within 1 hour.
Do not use if seals over carton ends are missing or broken.
Eli Lilly Australia Pty Ltd, Sydney, NSW

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ZYPREXA® is a registered trademark of Eli Lilly and Company

SH013SPNA03

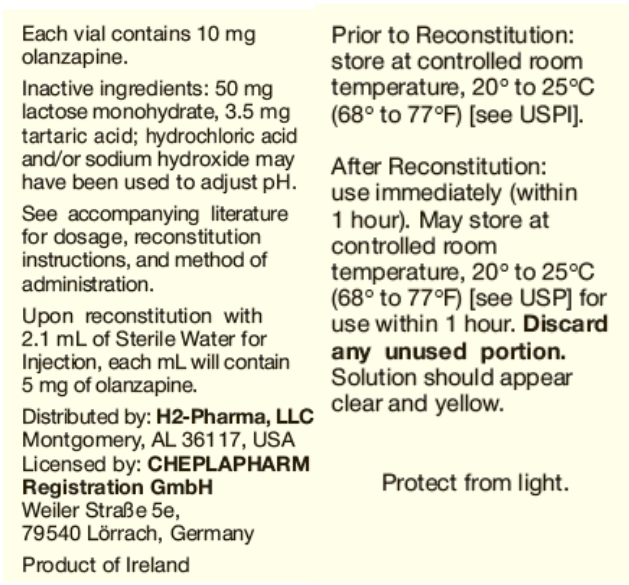
ZYPREXA® IM
Olanzapine 10 mg
powder for injection for I.M. use only

Each vial contains olanzapine 10 mg, lactose monohydrate 50 mg, tartaric acid 3.5 mg. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

Contains no antimicrobial agent. Use in one patient on one occasion only and discard any residue.

Store below 25°C.
Protect from light.

Vial stopper not made with natural rubber latex.



Each vial contains 10 mg olanzapine.

Inactive ingredients: 50 mg lactose monohydrate, 3.5 mg tartaric acid; hydrochloric acid and/or sodium hydroxide may have been used to adjust pH.

See accompanying literature for dosage, reconstitution instructions, and method of administration.

Upon reconstitution with 2.1 mL of Sterile Water for Injection, each mL will contain 5 mg of olanzapine.

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117, USA
Licensed by: **CHEPLAPHARM Registration GmbH**
Weiler Straße 5e,
79540 Lörrach, Germany

Product of Ireland

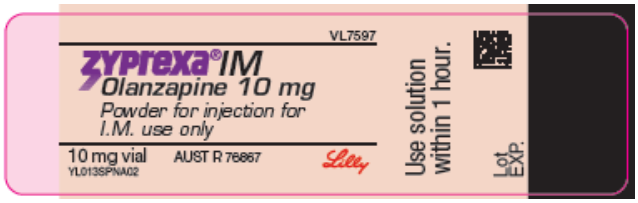
Prior to Reconstitution: store at controlled room temperature, 20° to 25°C (68° to 77°F) [see USPI].

After Reconstitution: use immediately (within 1 hour). May store at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP] for use within 1 hour. **Discard any unused portion.** Solution should appear clear and yellow.

Protect from light.

Vial artwork

Slight differences in name of product and additional wording on label



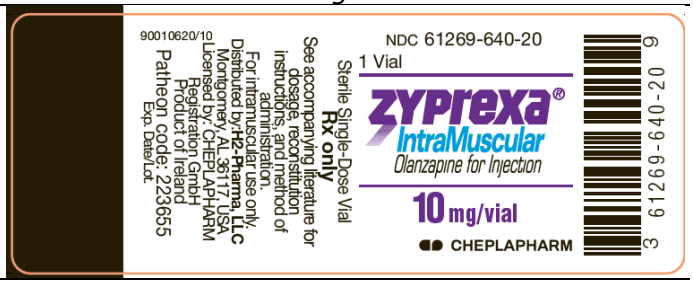
VL7597

ZYPREXA® IM
Olanzapine 10 mg
Powder for injection for I.M. use only

10 mg vial AUST R 76867
YL013SPNA02

Use solution within 1 hour.

Lot
EXP.



90010620/10
Pathegon code: 223655
Exp. Date/Lot:

Distributed by: H2-Pharma, LLC
Montgomery, AL 36117, USA
Licensed by: CHEPLAPHARM Registration GmbH
Product of Ireland

See accompanying literature for dosage, reconstitution instructions, and method of administration.
For intramuscular use only.

Sterile Single-Dose Vial
Rx only

NDC 61269-640-20
1 Vial

ZYPREXA®
IntraMuscular
Olanzapine for Injection
10 mg/vial

CHEPLAPHARM

3 61269-640-20 9

The overseas pack also contains a package insert which contains additional information to what is in the currently approved New Zealand Datasheet.

Zyprexa IM 10mg is indicated for the rapid control of agitation and disturbed behaviours in patients with schizophrenia and related psychoses and in patients with acute mania associated with Bipolar I Disorder, when oral therapy is not appropriate.

Please be advised that the dosage, indications and storage conditions remain the same as currently approved in NZ, and doctors and patients should ***disregard*** the information in the package insert and carton and refer to the New Zealand approved Datasheet, which is available via the Medsafe website:
www.medsafe.govt.nz/profs/datasheet/z/ZyprexaIMinj.pdf

If you have any medical enquiries, would like further information, or to report an adverse event, please contact Pharmaco (NZ) Ltd via safety@pharmaco.co.nz or phone 0800 80 4079. Any information regarding adverse events can also be reported to Medsafe via the following link: https://pophealth.my.site.com/carmreportnz/s/

Shirley Shen
Regulatory & Medical Associate