



**Bayer HealthCare**  
Consumer Care

**Proposal for Reclassification**

**of**

**Losec<sup>®</sup> & Losec<sup>®</sup>  
Extra Tablets**

**Omeprazole 10 mg & 20 mg**

**Extension of Maximum  
Pack Size to 28 Tablets**

**July 2011**



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## **PART A**

The current classification of the medicine omeprazole in New Zealand is:-

**Pharmacy Only**

In divided solid dosage forms for oral use containing 20 milligrams or less, with a maximum daily dose of 20 milligrams in a pack size of up to 14 dosage units, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine.

**Prescription**

Except when specified elsewhere in this schedule.

This submission to the Medicines Classification Committee proposes changing this current classification to:-

**Pharmacy Only**

In divided solid dosage forms for oral use containing 20 milligrams or less, with a maximum daily dose of 20 milligrams in a ***pack size of up to 28 dosage units***, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine.

**Prescription**

Except when specified elsewhere in this schedule.

Note that this proposal is only for an increase in the pack size restriction for the medicine, and is not a proposal to increase the duration of treatment for Losec or Losec Extra.

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Extension of the pack size restriction for Losec and Losec Extra as Pharmacy Only Medicines to 28 tablets is considered safe and appropriate in New Zealand for the following reasons:-

**Safety Profile/Toxicity** – omeprazole has an excellent safety record, with few serious or frequent side-effects or medicinal interactions, and little risk of masking serious disease. Providing the consumer with the option of purchasing more than one treatment in a single pack represents no increase in risk to the consumer.

**New Zealand Precedent** – the concept of offering more than one course of treatment in a pack of an over-the-counter medicine for short-term therapies is well-established and accepted in New Zealand

**International Precedents** – in many overseas countries omeprazole can be supplied in packs larger than 14 dosage units, particularly the 10 mg presentation. The current allowable pack sizes in Australia, the United States of America, Europe and the United Kingdom will be discussed.

**Consumer Convenience/Accessibility** – gastro-oesophageal reflux is a chronic condition which tends to remit and relapse. Due to this nature of the disease, it is logical and convenient to the patient that more than one course of treatment could be offered in a pack. The consumer would be offered an economical option of having another course of treatment “on hand” in the event of recurrence.

## **A1. Name of the Medicine**

The International Non-Proprietary Name of the medicine is omeprazole.

The proprietary or brand name of the product is Losec<sup>®</sup> (omeprazole 10 mg) and Losec<sup>®</sup> Extra (omeprazole 20 mg).

This application is specifically related to the tablets dosage form, containing omeprazole magnesium.

## **A2. Name of the Company**

This submission is made by:-

Bayer New Zealand Limited  
Consumer Care  
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Contact: Mr. Michael Campbell  
Senior Brand Manager – Losec

Bayer Consumer Care currently markets Losec tablets 10 mg as a Pharmacy Only Medicine in packs of 7 and 14 tablets, and Losec Extra 20 mg as a Pharmacy Medicine in packs of 14 tablets.

## **A3. Dose Forms, Strengths and Pack Sizes**

As stated above, the current classification of omeprazole is:-

### Pharmacy Only

In divided solid dosage forms for oral use containing 20 milligrams or less, with a maximum daily dose of 20 milligrams in a pack size of up to 14 dosage units, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine.

### Prescription

Except when specified elsewhere in this schedule.

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In order to gain approval from the Minister or Director-General for distribution as a Pharmacy Medicine, Medsafe have provided the following guidelines (effective as at 1 August 2011):-

### **Proton Pump Inhibitors**

- Do not use if you are experiencing weight loss, persistent regurgitation of food or vomiting, difficulty swallowing or symptoms of gastro-intestinal bleeding, except on medical advice.
- This product is for temporary use only [or] For short term use only
- Do not use this medicine for any purpose other than that specified on the pack, except on doctor's advice
- Consult a doctor before use if you are at risk of bleeding problems
- Do not use if you are pregnant except on the advice of a healthcare professional
- Consult a doctor if symptoms/condition persist(s), worsens or recur
- Consult a doctor if new or additional symptoms occur

Bayer considers these requirements reasonable and appropriate for omeprazole, and that they should be maintained. Extension of the allowable pack size to 28 tablets is consistent with these requirements.

Therefore, in terms of dose form, strength and pack size, it is proposed that tablets or capsules of omeprazole up to 20 mg be reclassified from to Pharmacy Medicine with maximum pack size limited to 28 tablets.

## **A4. Indications**

The current indication for omeprazole as a Pharmacy Medicine is:-

Short-term, symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over.

This indication is considered reasonable and appropriate for omeprazole as an over-the-counter medicine, and no change is proposed.

#### **A4.1 Dosage Recommendation**

The current dosage instructions on the carton label for Losec and Losec Extra tablets approved by Medsafe are:-

##### **Losec**

Take 2 tablets once daily until symptoms improve, then reduce the dose to 1 tablet once daily. If symptoms return, the dose may be increased to 2 tablets once daily.

Use the lowest dose that controls your symptoms.

##### **Losec Extra**

Take one tablet once daily. For best results, take Losec Extra for 14 days i.e. finish the pack.

Do not use for more than 14 days except on medical advice.

This same dosage recommendation is proposed for Losec 10 mg tablets, with addition of the advice currently approved for Losec Extra that a 14 day treatment duration will provide optimal results. The Losec Extra dosage instructions would change in that the reference to finishing the pack would be deleted. The proposed dosage instructions are:-

##### **Losec**

Take 2 tablets once daily until symptoms improve, then reduce the dose to 1 tablet once daily. If symptoms return, the dose may be increased to 2 tablets once daily.

Use the lowest dose that controls your symptoms.

For best results take Losec for 14 days.

##### **Losec Extra**

Take one tablet once daily. For best results, take Losec Extra for 14 days.

The statement “Do not use for more than 14 days except on medical advice.” will be removed as the warning required by the Medsafe guidelines is now “For temporary use only”.

## **A5. Classification**

The current classification of omeprazole, taken from the Medsafe Web site on 21 July 2011, is:-

Omeprazole, except when specified elsewhere in this Schedule	Prescription
Omeprazole; in divided solid dosage forms for oral use containing 20 mg or less, with a maximum daily dose of 20 mg in a pack size of up to 14 dosage units, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in packs approved by the Minister or the Director-General for distribution as a Pharmacy-Only Medicine	Pharmacy Only

The classification sought for omeprazole is:-

<b><i>Omeprazole, except when specified elsewhere in this Schedule</i></b>	<b><i>Prescription</i></b>
<b><i>Omeprazole; in divided solid dosage forms for oral use containing 20 mg or less, with a maximum daily dose of 20 mg in a pack size of up to 28 dosage units, for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over, when sold in packs approved by the Minister or the Director-General for distribution as a Pharmacy-Only Medicine</i></b>	<b><i>Pharmacy Only</i></b>



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Essentially, this submission supports and embraces all of the current restrictions for the non-prescription sale of omeprazole. The only change being proposed is that the allowable pack size be increased for omeprazole as a Pharmacy Medicine

### **A5.1 Classification Status in Other Countries**

Over the last decade there has been a world-wide trend towards removing restrictions on the sale of proton pump inhibitor medicines, in recognition of their favourable efficacy and safety profiles. This trend has been documented to the Medicines Classification Committee several times and is not repeated in this submission.

However, of interest to this submission is the allowable pack sizes for omeprazole as an over-the-counter medicine in other countries. Information is available for the following countries:-

#### **Australia**

Omeprazole is a Schedule 3 medicine in Australia, equivalent to a Restricted Medicine in New Zealand. The Schedule 3 entry is:-

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn, and other gastro-oesophageal reflux disease, in packs containing not more than 14 day's supply.

While not expressly stated, it is assumed that the maximum allowed daily dose is 20 mg omeprazole. Therefore, for omeprazole 10 mg, the Australian classification allows for a pack size of up to 28 dosage units. This proposal for New Zealand for a larger pack size is consistent with what is currently allowed in Australia for a 10 mg presentation.

#### **United Kingdom**

The current conditions for supply of omeprazole 10 mg as a Pharmacy Medicine in the United Kingdom were downloaded from the MHRA Web site on 21 July

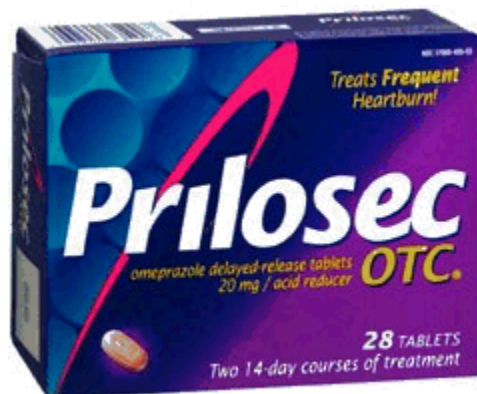
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2011 (see Appendix 1). The maximum daily dose of omeprazole allowed is 20 mg for a maximum of 4 weeks. The maximum allowed pack size is 28 tablets. This proposal for New Zealand for a larger pack size is consistent with the pack size currently allowed in the United Kingdom while still maintaining the more conservative duration of treatment of 14 days.

## United States

Omeprazole 20 mg has been available in the United States, effectively as a Pharmacy Medicine, since June 2003. It is available for periods of continuous use up to 14 days. While it is not clear if a maximum pack size is legislated, a pack of 28 tablets is permitted - the pack depicted below has been marketed in that country.



Note that this pack is positioned as two 14 day courses of treatment, and so is a model of what is proposed in New Zealand. A similar statement, also positioned on the front panel, is envisaged for New Zealand for the Losec Extra 28 tablet pack.

The very extensive OTC usage of omeprazole (see Section B1), including the availability of larger pack sizes, in the USA without the emergence of new safety issues is reassuring.

## European Countries

In most European countries, where omeprazole 20 mg is classified equivalent to Pharmacy Medicine, pack size is limited to the maximum duration of treatment which is 14 days. Thus, a pack size of 28 tablets is allowed for Losec 10 mg tablets, and a pack size of 14 tablets for the 20 mg presentation.

## **A6. Extent of Usage**

The extent of usage of omeprazole world-wide, both as a Prescription Medicine and as an OTC medicine, has previously been documented to the Medicines Classification Committee and is not repeated in this submission. Omeprazole has been extensively used in both settings and has proved to be a safe and reliable medicine when under the control of doctors, other healthcare professionals and consumers.

In New Zealand, Losec 10 mg tablets have been marketed as an over-the-counter medicine since October 2009, and in that time the equivalent of approximately 60,000 packs of 14 tablets have been sold. Losec Extra 20 mg has been marketed since November 2010 and approximately 16,000 packs have been sold. Since launch, Bayer New Zealand Limited has been notified of only one adverse event (constipation) associated with Losec purchased over-the-counter. This reporting reinforces the very good safety profile of omeprazole, already known for the product as a prescription medicine in New Zealand and as an OTC product in other countries. It strongly suggests that availability of the product over-the-counter in New Zealand has not led to an increased incidence of adverse events associated with the product.

## **A7. Labelling**

See below for the currently approved labelling (7 tablet pack) for Losec 10 mg tablets and Losec Extra 20 mg tablets. These labels will be adjusted slightly in future to better differentiate between the 10 mg and 20 mg strengths. Additionally, the warnings will be updated to meet the Medsafe requirements for proton pump inhibitors that come into effect on 1 August 2011.

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Virtually identical labels are envisaged for 28 tablet packs. As previously mentioned, the Losec Extra 28 tablet pack would have a statement on the front panel “Two 14 day courses of treatment.”

The pack insert would be a copy of the Consumer Medicine Information, very similar to the current CMI as provided in Appendix Two.

## **A8. Proposed Warnings**

Medsafe have provided the following required warnings for Proton Pump Inhibitors (effective 1 August 2011):-

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- Do not use if you are experiencing weight loss, persistent regurgitation of food or vomiting, difficulty swallowing or symptoms of gastro-intestinal bleeding, except on medical advice.
- This product is for temporary use only [or] For short term use only
- Do not use this medicine for any purpose other than that specified on the pack, except on doctor's advice
- Consult a doctor before use if you are at risk of bleeding problems
- Do not use if you are pregnant except on the advice of a healthcare professional
- Consult a doctor if symptoms/condition persist(s), worsens or recur
- Consult a doctor if new or additional symptoms occur

Bayer considers these warnings reasonable and appropriate for omeprazole, and that they would equally apply to the proposed pack size of 28 tablets. No additional warnings are considered necessary for the larger packs.

## **A9. Other Products**

In addition to Losec 10 mg and Losec Extra 20 mg tablets, there are a number of other omeprazole products registered to be sold in the New Zealand market as Pharmacy Medicines at the time of this submission. These are:-

<b>Brand Name</b>	<b>Strength and Pack Size</b>	<b>Sponsor Company</b>
Dr. Reddy's Omeprazole Modified Release Capsule	Capsule 10 mg	Dr Reddy's New Zealand Limited
Dr. Reddy's Omeprazole Modified Release Capsule	Capsule 20 mg	Dr Reddy's New Zealand Limited
Omeflux Modified Release Capsule	Capsule 10 mg	Dr Reddy's New Zealand Limited

These products might also be affected by this proposal for larger pack sizes, but this would be entirely the choice of the sponsor companies.

## **PART B**

This proposal to allow larger pack sizes of omeprazole tablets as Pharmacy Medicines, including the restrictions as outlined in Part A, does not include any additional relaxation of the classification of omeprazole. Reclassification of Losec 10 mg and Losec Extra 20 mg tablets to allow packs of 28 tablets as Pharmacy Medicines is considered appropriate for New Zealand because:-

***Suitable Safety Profile/Toxicity*** – omeprazole has an excellent safety record, with few serious or frequent side-effects or medicinal interactions. Providing the consumer with the option of purchasing more than one treatment in a single pack represents little increase in risk to the consumer.

***Low Risk of Masking Serious Disease*** – since treatment guidelines for heartburn/dyspepsia without alarm symptoms recommend treatment with full dose PPI's for a month before further investigation, consumer self-treatment with Losec or Losec Extra does not pose a risk of delayed investigation or treatment of serious disease, even if the consumer ignores the pack warnings and uses the entire proposed pack of 28 tablets.

***New Zealand Precedent*** – the concept of offering more than one course of treatment in a pack of an over-the-counter medicine for short-term therapies is well-established and accepted in New Zealand

***International Precedents*** – in many overseas countries omeprazole is available in packs larger than 14 dosage units.

***Consumer Convenience, Accessibility and Economy*** – gastro-oesophageal reflux is a chronic condition which tends to remit and relapse. Due to this nature of the disease, it is logical and convenient to the patient that more than one course of treatment could be offered in a pack, and this would be a cost-effective option for them. The consumer would be offered the option of having another course of treatment “on hand” in the event of recurrence.

Many of the usual considerations taken into account for reclassification of a medicine, such as the suitability of the indication, ease of self-diagnosis, possibility of resistance, possibility of abuse, medicinal interactions, etc. have already been resolved for omeprazole and so are not discussed further in this submission.

Reclassification of Losec 10 mg and Losec Extra 20 mg tablets to allow a 28 tablet pack size will offer consumers improved choice and convenience with very little increase in the risk of unwanted side effects, medicinal interactions or masking of serious disease. It would offer Losec consumers a more cost-efficient pack size, and the opportunity to have a full course of treatment for the 10 mg presentation, and a course of treatment “on hand” for the 20 mg presentation. The potential to have a course of treatment available is appropriate for this medication due to the sporadic recurrent nature of the disease.

Risk to benefit analysis favours the proposed reclassification.

## **1. Safety Profile**

Omeprazole has a broad therapeutic window and the safety profile for the approved over-the-counter indications is both well established and satisfactory. The safety and tolerability of omeprazole when self-administered is demonstrated by its record of safe use in the pharmacy environment, both in New Zealand and in many other countries since 2003.

The safety profile of omeprazole has been presented and discussed with the Medicines Classification Committee on several occasions previously, and is now considered well-demonstrated and accepted for New Zealand. Further discussion of this area would be unnecessarily repetitive. However, there is new data available from the USA regarding medicine interactions that has not previously been presented to MCC, as outlined below.



Since 2003 omeprazole 20 mg has been available in the USA as a non-prescription medicine (Prilosec OTC) with a maximum treatment period of 14 days. Non-prescription status in the USA allowed self-selection of medicines without the intervention of a pharmacist and is thus a similar setting to Pharmacy Medicine in New Zealand. The table below gives the total volume of usage since launch in the USA as well as the total adverse events classified as potentially due to drug interactions from the PSURs for Prilosec OTC from launch until the latest period:-

***Volume of Usage (14 day courses sold) for Prilosec OTC in the USA and Reports of AEs Based on Suspected Interactions***

<b>Reporting Period Summarised</b>	<b>Number of 14 Day Courses at 20 mg (millions)</b>	<b>Number of AE Reports Based on Suspected Interactions</b>
21/06/2003 – 15/04/2010	520.66	43 total 0 serious

Self-medication with Prilosec OTC has been very extensive. Despite this, reports of adverse events classified as potentially due to drug interactions have been sparse. All of the accumulated 43 reports were designated as not serious and all were consumer generated and not medically confirmed. Consequentially limited information is provided in the reports, many of which contain potential confounders e.g. multiple co-administered medications and underlying medical conditions which provide alternative possible explanations for the observed events, and mean that causality cannot be established with any certainty.

The reports include diverse symptoms and manifestations, and no pattern or trend is evident. With regards to the suspected drug involved in the interaction, more than one report was received for warfarin (11 reports), diazepam (14 reports) and digoxin (2 reports) respectively; however, these reports lack details of symptoms or laboratory values.

The overall experience from this extensive non-prescription usage is in accordance with the established safety profile of omeprazole. Review of the reports received during the period since launch does not identify any new trends or evidence of new potential drug interactions. The reports contained confounding factors, alternative causes or insufficient information for causality assessment. In addition, many of the reports either described AEs that were already listed in the prescription label for omeprazole in the USA or that have been associated directly with the co-suspect or concomitant therapies.

In overview, omeprazole does not present a special hazard to health, and even substantial overdosage does not result in serious clinical consequences. The risk of organ toxicity arising from inadvertent or intentional overdosage is very small – even after consuming the entire contents of a complete proposed OTC pack (560 mg omeprazole in a 20 mg 28 tablet pack). The symptoms reported after an overdose have been transient, without lasting sequelae and generally do not require any treatment.

## **2. Risk of Masking Serious Disease**

In the event that there is incorrect self-diagnosis, the patient would not unduly aggravate the condition as the label instructs the patient to seek medical advice if symptoms persist, worsen or recur and emphasizes that continuous treatment should not exceed 14 days. This reflects a balance between dosing for long enough to achieve an optimal effect and avoiding the risk of masking or delaying diagnosis and treatment of a more serious condition.

Population surveys in Western populations suggest that around 30% of sufferers have heartburn at least monthly, while 20% suffer weekly and 7% daily (1). Despite this, only 25% of all heartburn sufferers in the United Kingdom consult a doctor (2). There is poor correlation between severity of symptoms and endoscopic appearances – 70% of heartburn patients will have an apparently normal oesophageal mucosa (3, 4). For this reason, current clinical guidelines (5, 6) recommend a symptom based approach, and investigation (in the form of endoscopy) is reserved for those sufferers with alarm symptoms that may indicate a more serious underlying disease. These alarm symptoms are identified for consumers on the Losec labeling, with the advice to see a doctor if present – thus, consumers are enabled to identify potential alarm symptoms and act appropriately.

It is appropriate to focus on these alarm symptoms and to have prominent warnings to alert consumers to them. In the absence of alarm symptoms, current prescribing guidelines recommend empirical treatment with a PPI at full dose for one month (5, 6). Consumer self-treatment with a PPI has previously been accepted as not posing a risk of masking serious underlying disease because in the absence of alarm symptoms current medical treatment would be to first try PPI treatment.

The proposed increase in allowed pack size is entirely consistent with this argument. While the labeling instructs the consumer to restrict the treatment period to 14 days, it is acknowledged as possible that a consumer might ignore

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this advice and continue treatment with the whole pack. However, as a pack size of 28 tablets of omeprazole 20 mg represents at most one month's treatment, such usage would be exactly what a doctor following current guidelines would do. As such, should symptoms persist, the patient's progression to further investigation or treatment would not be delayed.

The great majority of people with heartburn in the community will have a normal oesophageal appearance if subjected to endoscopy (3, 4). Furthermore there is consensus that normal or even mild to moderate erosive mucosal changes do not appear to progress to more erosive disease (4, 7) – thus, there is confidence that the possibility of underlying malignancy is negligible in the absence of alarm symptoms.

In rare cases severe erosive disease can lead to long term complications (such as stricture formation or dysplastic changes). However, severe erosive disease can generally be identified on the basis of symptom response, requiring continuous, long term and often high dose treatment to achieve healing and to control symptoms. The proposed Losec and Losec Extra labeling warns against such treatment. The proposed pack size increase is considered very unlikely to promote self-treatment of this extent. The risk of such self-treatment would not be increased by the pack size increase proposed, since such it would still require multiple purchases of many packs.

The treatment of acid related reflux symptoms with General Sales or Pharmacy medicines is well established in New Zealand. In particular antacids and antacid/alginate products have been available general sales supply for many years, and more recently H<sub>2</sub> receptors have become available for general sales supply. All of these existing treatments have the capacity to temporarily relieve the symptoms of more serious disease e.g. erosive oesophageal disease or ulcerated gastric malignancy. The introduction of omeprazole as an OTC medicine did not introduce significant new risk in this regard. Similarly, the introduction of a larger pack size of omeprazole as a Pharmacy Medicine does not introduce additional risk, especially as the Losec Extra label will emphasize that the pack contains more than one treatment.

In summary, the incremental risk to consumers of masking serious disease from increasing the allowed pack size of omeprazole from 14 tablets to 28 tablets is considered minimal

### **3. New Zealand Precedent**

Increasing the maximum permitted pack size of omeprazole in New Zealand represents little change from the status quo, apart from the concept that more than one treatment might be contained within a pack. However, while a new concept for OTC omeprazole this is a common concept for over-the-counter medicines generally.

In particular, consumers are well-familiar with more than one treatment being contained within a pack for analgesics – most analgesic pack sizes contain more than one treatment, and consumers are familiar with stocking the remainder of the pack for future use. Analgesic pack sizes are determined by toxicity in overdose concerns, the primary consideration being the effect if a child took the entire pack. If this approach were to be applied to omeprazole, a pack size of 28 tablets (i.e. potentially 560 mg omeprazole) would be allowable. In the literature doses of up to 560 mg have been described and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose).

The provision of more than one treatment in a pack is also well-established in the therapeutic area of indigestion and heartburn, with antacids frequently being supplied in large packs (up to 36 tablets). This is reflective of the recurrent nature of the disease, and the desire of many sufferers to have a treatment “on hand” should they experience a relapse of their symptoms.

### **4. International Precedent**

Please refer to Section A5.1 for a listing of the relevant overseas classification status for omeprazole in relation to allowable pack sizes. Of the countries that have been surveyed, New Zealand is the only country that currently restricts the allowable pack size for omeprazole 10 mg to 14 tablets – in all other countries a pack of 28 tablets would be possible.

Further, the United States allows pack sizes of 28 tablets, although it is unknown if there is a maximum pack size stipulated. This is of particular relevance as the USA is also the country that has the most liberal system in terms of omeprazole availability and has the longest and most extensive experience with non-prescription omeprazole. This more liberal system, with less pharmacist

supervision and the availability of multiple-treatment pack sizes, does not appear to have resulted in increased incidence of adverse events, medicine interactions or overdose.

## **5. Consumer Convenience, Accessibility and Economy**

In 2008, Bayer Consumer Care conducted market research in a sample of 3,000 heartburn sufferers recruited from the United Kingdom, France and Germany (1,000 from each). As an essentially European sample, the results of this survey are expected to be a reasonable representation of the situation in New Zealand as well.

Of this total sample, 54% suffered heartburn more than twice per week, whilst 20% suffered symptoms daily. In the group suffering heartburn frequently (more than twice per week) and purchasing medications over-the-counter, the following features were apparent when compared to the broader population of sufferers:

- this group is the most likely to self-medicate (49% feel confident vs. 43%).
- they are more likely to use their OTC products daily (48% vs. 29%).
- they medicate on almost every symptom occurrence (86% vs. 70%).
- they are more likely to use strong antacids or H<sub>2</sub> receptor antagonists (e.g. ranitidine usage 12% vs. 4%).
- despite treating their condition, a higher proportion of this group reported continued symptoms (38% vs. 27%).
- of this group, 26% buy OTC products due to the convenience of not having to go to the doctor vs. the total sample average of 16%.
- 44% of these consumers buy OTC products more than once per month, vs. 19% of all sufferers.

Not surprisingly, this survey suggests that frequent heartburn sufferers become confident in self care of their symptoms. However, despite treating frequently, many fail to control their heartburn completely (note that this research was carried out before PPIs were available OTC in Germany, around the time they became available in France, and - although available - OTC usage in the United Kingdom was very low). The use of antacids and H<sub>2</sub>RAs in this frequently suffering population is unlikely to produce complete relief of symptoms.

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Frequent heartburn, defined as more than twice a week but not daily, is treated optimally with PPIs dosed daily for 14 days. It is probable that frequent sufferers, by virtue of their need to make frequent purchases due to the remit and relapse nature of the disease, are also likely to particularly value the convenience of purchasing their medicine without the need to always make a visit to a pharmacy. A larger pack, offering more than one treatment, would be convenient for these people.

Furthermore, for frequently sufferers of heartburn the onset of an attack is often a “crisis” situation, as the sufferer knows that without rapid treatment symptoms are likely to escalate and become very uncomfortable. With this knowledge, many sufferers keep medication on hand so that immediate action can be taken at the onset of symptoms. It is likely that these patients are already keeping Losec or Losec Extra “on hand”. The proposed larger pack sizes would assist these consumers.

While the current classification of omeprazole limits the pack size, there are few barriers to the patient purchasing more than one pack that would not also exist for a patient purchasing a larger pack. The pharmacist/pharmacy assistant would still be available as a gatekeeper to check the appropriateness of the purchase whether the patient was purchasing two smaller packs or one larger pack.

Naturally a larger pack could offer patients a more favorable price per tablet, thereby lowering the cost of treatment and increasing the cost effectiveness of Losec or Losec Extra.



## **APPENDICES**

### **Appendix One**

Conditions for “P” supply in the United Kingdom.

### **Appendix Two**

Current Consumer Medicine Information for Losec and Losec Extra as a Pharmacy Only Medicine.

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