Submission for Reclassification

Solox Relief

(lansoprazole 15 mg)

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July 2008

Executive Summary

This application seeks approval to change the current classification of Solox 15 mg (lansoprazole) from Prescription Medicine to Pharmacist Medicine (OTC) for short-term symptomatic relief of reflux-like symptoms. It is also proposed that this product will be marketed as Solox Relief should the proposed re-classification be approved.

This request for reclassification of Solox Relief 15 mg (14 pack) is supported by the 1990 Commission of the European Communities, as discussed in the New Zealand Regulatory Guidelines[1], regarding the OTC sale of medicines.

Lansoprazole has been available locally and internationally for many years and has a well-documented safety and efficacy profile for both the provision of relief and the prevention of recurrence of heartburn and indigestion. The reclassification to Pharmacist Medicine will allow appropriate patients simpler access to this medication and superior resolution of symptoms upon treatment compared to alternative strategies. This, however, should only occur after an appropriate consultation with a pharmacist.

Consumer convenience

The relief and prevention of heartburn and indigestion is suitable for self-treatment as it is generally due to a minor cause (not requiring medical intervention) and is often self-limiting. The reclassification of Solox Relief 15 mg (14 pack capsules) to OTC medicine for symptomatic relief and prevention of heartburn and indigestion will increase the accessibility to OTC treatment for a self-diagnosed and self-treatable condition.

Most persons suffering from heartburn or indigestion prefer a prompt and effective treatment. Proton pump inhibitors (PPIs) have proven to be an effective treatment of these common symptoms [2-20]. This application recommends sale as a Pharmacist medicine, removing the need to wait in GP rooms and the expense of a doctor's fee for those patients the pharmacist deems to be suitable for self-medication.

In addition, self-care for these common symptoms features prominently among the New Zealand population with 69% of those with reflux-type symptoms using over-the-counter medications such as antacids [21]. A proportion of consumers are unsatisfied with antacids or H_2 antagonists and these consumers would benefit from the availability of lansoprazole as a Pharmacist medicine.

Potency

Lansoprazole has demonstrated efficacy in the treatment of heartburn and other symptoms of indigestion that has been well documented in numerous published clinical studies [3-14]. It is also well documented that heartburn and other symptoms related to gastric hyperacidity are extremely common in the general population [22,23].

Heartburn and acid regurgitation are common symptoms of gastro-oesophageal reflux, being the result of one or more physiological factors affecting the competence of the gastro-oesophageal junction [24]. Reflux of the acidic gastric contents into the lower oesophagus produces the classic symptoms of heartburn and acid indigestion. Other symptoms such as epigastric pain are also common.

The occurrence of heartburn is related to the magnitude of the pH decrease and heartburn only occurs when reflux is associated with oesophageal pH below 3. Many persons with reflux remain unseen by healthcare professionals as they manage their symptoms through conservative measures that require no medical intervention.

Prevalence, severity and associated features of both reflux and dyspepsia in the New Zealand general population are well known with a combined overall prevalence of ‘significant’ symptoms of dyspepsia and reflux being 45% [21].

While this prevalence appears high it is in agreement with other published studies. In the UK dyspepsia prevalence is reported to be 40% [25]. The most

commonly reported symptom in New Zealand is heartburn at 70% [21]. This is in agreement with international sentiment, which reports heartburn as being the most common symptom of reflux in at least 75% of persons [26,27].

Following reclassification from Prescription-only to Pharmacist Medicine status Douglas Pharmaceuticals Ltd proposes to undertake a comprehensive educational campaign with pharmacists regarding the use of PPIs for heartburn and dyspepsia. This will include which patients should be referred to a GP, the potential for adverse events and drug interactions, which patients would be more suitable for an antacid or H_2 antagonist and which patients would benefit from treatment with Solox relief.

Evidence for the use of lansoprazole 15 mg

Lansoprazole has been studied in numerous clinical trials involving treatment of patients with heartburn and reflux like symptoms [3-14].

Of particular note Gough et al compared the relative efficacies of lansoprazole 15 mg once daily (and lansoprazole 30 mg once daily) to ranitidine 300 mg bd in the treatment of reflux oesophagitis [10].

Patients with grade 0, asymptomatic oesophagitis after 8 weeks of treatment with lansoprazole 30 mg once daily were randomised to receive lansoprazole 15 mg once daily (n=86), lansoprazole 30 mg once daily (n=75) or ranitidine 300 mg bd (n=74) for 12 months.

Endoscopy was undertaken at 6 and 12 months, and symptomatic assessment was made every 3 months. Efficacy was primarily assessed by the time to endoscopically confirmed relapse (oesophagitis grade>=1) and the proportion of patients who relapsed during the 12-month study period. Severity of symptoms were secondary efficacy measures.

For all patients randomised with at least one post-baseline endoscopy (intent-to-treat principle) both lansoprazole 15 mg (P<0.001) and lansoprazole 30 mg (P<0.001) were significantly superior to ranitidine 600 mg with respect to time to endoscopic relapse. There was no difference between the lansoprazole groups (P=0.11).

Patients receiving treatment with either lansoprazole dosages experienced significantly less severe heartburn and regurgitation than those patients treated with ranitidine. There were no differences between the treatment groups with respect to the severity or incidence of adverse events. No clinically significant laboratory changes were observed in any of the treatment groups. Serum gastrin levels were elevated in all treatment groups, and most markedly in those patients receiving lansoprazole, but there was no significant difference between the treatments. Morphological and immunohistochemical examination of the gastric biopsies revealed no clinically relevant changes from baseline in any of the treatment groups.

Similarly, the intermittent on-demand treatment of patients for heartburn with the PPI omeprazole has been assessed in a number of trials [16,20,28].

The efficacy of intermittent on-demand omeprazole 10 mg versus ranitidine 150 mg was assessed by Bardhan in a trial of 677 patients randomly assigned to omeprazole 10 mg or 20 mg daily or ranitidine 150 mg twice daily for two weeks [28].

At the end of the two weeks of treatment the proportion of patients without symptoms was 40% for omeprazole 10 mg, and 26% for ranitidine 150 mg twice daily (p<0.001). The relative risk (RR) of remaining symptomatic on omeprazole 10 mg once daily compared to ranitidine 150 mg bid was 0.80 (or 0.59/0.74) with an Absolute Risk Reduction (ARR) of 0.15 (0.74–0.59). Those patients not responding to initial therapy could be readily self-identified by their on-going symptoms and would be candidates for further investigation.

The relative efficacy of lansoprazole 15 mg once daily has also been compared to omeprazole 10 mg once daily in relieving heartburn and epigastric pain [12]. The double-blind, parallegroup, multicentre study was conducted in 52 general practices in the United Kingdom with 609 patients recruited and 562 eligible for inclusion in the intent to treat analysis. All patients had experienced at least mild heartburn or mild epigastric pain persistently on at least 4 of the previous 7 days; patients with severe symptoms were excluded.

In the intention to treat population, complete relief of overall primary symptoms of dyspepsia was achieved after two weeks in 53% of patients receiving lansoprazole and in 41% of patients receiving omeprazole (p=0.007). In addition antacids were taken for relief of symptoms in fewer patients given lansoprazole compared to the omeprazole group (p=0.035).

Current availability

Currently, there are no other products available as Pharmacist Medicines on the New Zealand market with the same active ingredient (lansoprazole) or indeed from the same therapeutic group of products (proton pump inhibitors). The Medicine Classification committee has, however, considered the reclassification of omeprazole from a Prescription Medicine to Pharmacist Medicine on a number of occasions.

There are no other products currently marketed in New Zealand with the same active ingredient.

Other products available OTC which are used to treat the symptoms of heartburn or indigestion, with varying degrees of efficacy, include low dose H_2 receptor antagonists, antacids and alginates.

Therapeutic index

Lansoprazole is known to have a very wide therapeutic index and the risk of adverse events occurring is low when taken at the recommended therapeutic

doses.

Toxicity

No concerns regarding toxicity are expected with the use of lansoprazole. Many published studies have demonstrated the favourable safety profile of lansoprazole and of the proton-pump inhibitors as a class [2-20]. While recent publications have shown increased reports of interstitial nephritis as a hypersensitivity reaction to Proton Pump Inhibitors, the incidence of lansoprazole induced interstitial nephritis is rare and when it does occur it tends to do so after more than 2 weeks of treatment. Nevertheless appropriate warnings are included in the proposed labelling and package insert.

Abuse potential

Lansoprazole has a very low potential for abuse or misuse. The classification of Solox Relief 15 mg will be Pharmacist Medicine and therefore, any potential for abuse or misuse can be expected to be minimal.

Inappropriate use

The classification of Solox Relief 15 mg will be Pharmacist Medicine hence requiring consumer purchase over the counter and interaction with a pharmacist prior to its sale. This process will ensure appropriate use and minimise the risk of misdiagnosis. Furthermore inappropriate use of lansoprazole is not anticipated upon reclassification due to its very low potential for misuse or abuse.

Precautions

Precautions are detailed in the medicine data sheet, package and package insert.

Communal harm

The wider availability of this medicine is not expected to increase harm to the community due to its low potential for abuse or misuse as we propose a Pharmacist Medicine classification. There is no evidence to suggest that wider

availability of lansoprazole would lead to increased resistance or to the development of tolerance.

Part A

1. International Non-proprietary Name of the medicine.

Lansoprazole

2. Proprietary name.

Solox Relief

3. Name of company requesting reclassification.

Douglas Pharmaceuticals Limited

4. Dose form and strength for which a change is sought.

Capsule, modified release
Strength: 15 mg modified release capsules

5. Pack size and other qualifications.

Blister packs of 14 capsules
Two capsules to be taken at the same time on days one and two followed by one capsule daily until completion. It is recommended to take Solox Relief capsules in the morning.

6. Indications for which change is sought.

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

7. Present classification of medicine.

Prescription Only Medicine

8. Classification sought.

Pharmacist Medicine

9. **Classification status in other countries**.

Lansoprazole is a Prescription Medicine in all other jurisdictions, although application for OTC usage has been made in the USA. Omeprazole is registered for OTC usage in the following jurisdictions.

Country of Registration	*Classification*
Sweden	OTC 10 mg (since 1999)
United Kingdom	OTC 10 mg (since 2004)
United States	OTC 20 mg (since 2003)

10. Extent of usage in NZ and dates of original consent to distribute.

Lansoprazole was first registered in NZ in 1994. Solox 30 mg (Douglas Pharmaceuticals Ltd) was given Consent as a Prescription Medicine in New Zealand on 21 October 2004. Solox 15 mg was given Consent on 3 August 2006.

Sales volumes for PPIs during the last five years in New Zealand have been as follows:

	Annual Sales to Apr 2004	Annual Sales to Apr 2005	Annual Sales to Apr 2006	Annual Sales to Apr 2007	Annual Sales to Apr 2008
	Units	Units	Units	Units	Units
SOMAC	474,100	458,457	478,305	470,160	388,501
SOMAC TABS 40 mg 28	279,413	272,091	293,868	303,069	251,120
SOMAC TABS 20 mg 28	194,687	186,366	184,437	167,091	137,381
OMEZOL					525,023
OMEZOL CAPS 10 mg 30					26,972
OMEZOL CAPS 20 mg 30					414,109
OMEZOL CAPS 40 mg 30					83,942
OMEPRAZOLE DR REDDY					18,891
OMEPRAZOLE 10 mg 28					857
OMEPRAZOLE 20 mg 28					13,722
OMEPRAZOLE 40 mg 28					4,312
PANTOPRAZOLE DR REDDY					67,513
PANTOPRAZOLE 20 mg 28					25,160
PANTOPRAZOLE 40 mg 28					42,353
SOLOX				25,094	44,024
SOLOX CAPS 30 mg 28				24,697	37,553
SOLOX CAPS 15 mg 28				397	6,471
LOSEC	2,130,775	2,393,822	2,680,682	2,892,189	2,614,387
LOSEC CAPS 10 mg 30	117,656	134,511	144,357	149,507	137,238
LOSEC CAPS 20 mg 30	1,737,068	1,914,369	2,106,818	2,245,785	1,990,940
LOSEC CAPS 40 mg 30	241,885	304,289	378,765	444,279	429,560

11. Labelling or draft labelling for the proposed new presentation.

Draft labelling is provided (Appendix 1). These will be submitted to Medsafe for assessment and registration only after confirmation of change in classification.

12. Proposed-warning statements if applicable

(Copy to be included in the proposed pack insert is attached in Appendix 2)

The information in the insert is in accordance with the previously approved medicine datasheet with additional directions in relation to the proposed reclassification.

Before you take SOLOX RELIEF

When you must not take it

Do not take SOLOX RELIEF if:

- You are allergic to lansoprazole or other proton pump inhibitors such as omeprazole and pantoprazole.
- You are allergic to any other ingredients in SOLOX RELIEF.
- You have or have had severe liver disease.
- You are pregnant or intend to become pregnant.
- You are breast-feeding or intend to breast-feed. SOLOX RELIEF should not be used during pregnancy or while breast-feeding, as it may affect your baby.

If you are not sure whether you should start taking SOLOX RELIEF, talk to your pharmacist or doctor.

Do not use it after the expiry date (EXP) printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use SOLOX RELIEF if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your pharmacist if you have allergies to:

Other medicines

Other substances, such as foods, preservatives or dyes.

If you have not told your pharmacist about any of the above, tell him/her before you start taking SOLOX RELIEF.

Taking other medicines

Tell your pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with SOLOX RELIEF or vice versa.

These include:

Theophylline used to treat asthma

Oral contraceptives

Carbamazepine used to treat epilepsy

Warfarin used to thin the blood

Phenytoin used to treat seizures or heart rhythm disorders

These medicines may be affected by SOLOX RELIEF, or may affect how well it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your pharmacist can advise you on this.

13. Other products containing the same active ingredient and which would be affected by the proposed change.

The following prescription medicines are registered with Medsafe and contain lansoprazole 15 mg.

- Zoprol modified release capsules 15 mg (SFY Ltd)
- Zoton modified release capsules 15 mg (Wyeth NZ Ltd)

As this application is for an additional classification, it will not have any direct effect on the status of these products.

Part B

Reasons for requesting classification change.

1. Benefits to both the consumer and to the public expected from the proposed change.

Data from the New Zealand IMS Medical Index suggests increasing use of PPIs for the management of heartburn and dyspepsia with PPIs surpassing the number of prescriptions for both H_2-antagonists and antacids combined.

The current rate of growth in the proton pump inhibitors (PPI) market is approximately 8% according to IMS data. Furthermore, PHARMAC data suggests that there are 220,000 (patient year equivalents - PYEs) prescribed a PPI with about 35,000 new patients being introduced to a PPI each year.*

The reclassification of Solox Relief 15 mg as an OTC medicine will allow the management of a proportion of patients who have simple, uncomplicated, mild heartburn and reflux.

While there would be an obvious potential saving in the direct cost of anti-ulcerant pharmaceuticals to the Government this is insignificant compared to the benefit for consumers for whom the availability of Solox Relief 15 mg will remove both the cost of GP consultations and the use of therapies with sub-optimal efficacy [46,47].

2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated.

A large proportion of reflux sufferers, and those with acid-related symptoms, self-medicate without medical advice [21]. The widespread availability of antacids and H_2 antagonists for these conditions as OTC or general sale medicines throughout the world attests to the belief of many people that

* Pharmac figures Gut Reaction website

they are able to self-diagnose such conditions and that self-medication is appropriate. In New Zealand it is estimated that approximately 70% of subjects with reflux-like symptoms already self-medicate [21].

The low dose (30 mg on days one and two followed by 15 mg) and short duration (12 days) of Solox Relief therapy is unlikely to heal active peptic ulceration or severe oesophagitis. Symptoms are likely to recur which will force the consumer to seek medical advice. It is not likely that this short-term delay in seeking medical advice would affect subsequent prognosis[48,49]. Studies have shown that approximately 91% of patients presenting with persistent post-prandial heartburn and who underwent endoscopy [50] were free of erosions and ulcers, therefore, the risk of masking severe disease in this self-diagnosing population is minimal.

The use of PPIs as empirical therapy for the management of dyspepsia and heartburn is well established in New Zealand, furthermore, PPIs have been available in New Zealand since 1990 with many millions of prescriptions being written over that time [42-45].

Additionally The British Society of Gastroenterology [23] defines dyspepsia as a group of symptoms that alert doctors to consider disease of the upper gastrointestinal tract. It is not a diagnosis but includes symptoms of upper abdominal discomfort, retrosternal pain, anorexia, nausea, vomiting, bloating, fullness, early satiety and heartburn amongst others. Many diseases are known to cause dyspepsia and these include peptic ulcers, oesophagitis, cancer of the stomach or pancreas, and gallstones. In a large proportion of cases no clear pathological cause for a patient's symptoms can be determined. The prevalence of dyspepsia is high in Western societies (20-40%) [23,51] and the majority of sufferers do not consult a doctor [23]. Episodic heartburn and indigestion related to food and drink are conditions easily recognisable by the consumer and the condition is unlikely to be serious and in such cases immediate symptom relief will be sought and not a course of treatment. The British Society of Gastroenterology [23] advises that it is acceptable to institute a single course of treatment with an

anti-secretory agent for 2-4 weeks in such patients who have troublesome symptoms but without “alarm” symptoms. The above symptoms are easily recognised by the patient in combination with their pharmacist. Therefore, consumer self-diagnosis followed by consultation with their pharmacist and a short-term treatment with low dose Solox Relief could be expected to be both an acceptable and effective intervention.

Appropriate warnings will be provided on the packet and packet insert [See appendixes 1 and 2]. While the majority of consumers are likely to heed those warnings, in those who do not, it is unlikely that the level of risk will increase significantly.

Following reclassification from Prescription Medicine to Pharmacist Medicine status, Douglas Pharmaceuticals Ltd proposes to undertake a comprehensive educational campaign with pharmacists regarding the use of PPIs for heartburn and dyspepsia. This will include which patients should be referred to a GP, the potential for adverse events and drug interactions, which patients would be more suitable for an antacid or H_2 antagonist and which patients would benefit from treatment with Solox relief.

Guidance borrowing heavily from the Practice Division of the Royal Pharmaceutical Society of Great Britain along with training by the Douglas Pharmaceuticals Ltd Pharmacy field force will be undertaken with NZ pharmacies in the months prior to launch of the product in New Zealand.

A draft guideline on best practice is attached in Appendix 3. Prior to printing and distributing this in NZ, further input will be sought from the NZ Pharmaceutical Society of New Zealand as well as permission to reproduce sections from the Practice Division of the Royal Pharmaceutical Society of Great Britain.

3. Relevant comparative data for like compounds.

Discussion of comparative data discussion has been presented under “Evidence for the use of lansoprazole 15 mg” in the previous section.

Like compounds available for relief of similar symptoms include antacids which are general sale medicines. Antacids produce a short-lived effect on gastric pH and may cause diarrhoea, constipation or reduce the absorption of some medicines due to changes in gastric pH.

Alginates seem to be more useful than antacids in controlling symptoms, but no placebo-controlled study has shown healing of oesophagitis with either of these classes [46].

Muco-protective agents such as sucralfate act locally by shielding damaged mucosa or stimulating local defence mechanisms. One problem is that swallowing induces oesophageal peristalsis so reducing mucosal protective time.

Motility stimulants, for example Cisapride - the one stimulant that is well studied, have a principal effect on oesophageal acid clearance. They appear to be effective in grades 1 and 2 oesophagitis but efficacy on more severe disease is not proven [47].

The H_2 antagonists available OTC are ranitidine 75 mg and famotidine 10 mg. OTC H_2 antagonists are approved for short-term symptomatic relief of heartburn, dyspepsia and hyperacidity. However, PPIs have shown significantly better rates of resolution of heartburn symptoms and relapse when compared to ranitidine in the management of acute and maintenance treatment of reflux disease [52].

4. Local data or special considerations relating to NZ.

The proposed reclassification would allow the consumer easier access to rapid treatment for easily self-diagnosed symptoms, after a suitable consultation and confirmation by a pharmacist. This will avoid a proportion of unnecessary GP visits and provide a more timely treatment for self-diagnosed and manageable symptoms.

5. Interactions with other medicines.

There are three known mechanisms by which lansoprazole can cause drug interactions:

(a) *pH dependent drug absorption:* Lansoprazole causes a profound and long lasting inhibition of gastric acid secretion; therefore, it is theoretically possible that lansoprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. ketoconazole, ampicillin esters, iron salts, digoxin).

(b) *Inhibition of CYP450 enzyme metabolism*: Lansoprazole is metabolised in the liver and is a weak inducer of cytochrome P450. Therefore, there is the possibility of interaction with other drugs metabolised via this system e.g. theophylline. Patients receiving such drugs concomitantly with lansoprazole should be monitored to determine if any dosage adjustment is necessary.

While hypochlorhydria may result in malabsorption of fat, vitamin B12 and iron, in the vast majority of cases this has not been found to be of clinical relevance. However a small percentage of patients on long-term treatment have been found to have reduced serum B12 levels.

Hypochlorhydria has also been thought to weaken the stomach's defence and cause bacterial overgrowth and enteric infection, but the significance of this has not been confirmed [55]. It is known that PPIs raise gastrin levels up

to four times baseline level [31] and that these levels are higher with PPIs than with H_2 antagonists.

Secondary hypergastrinaemia has led to concerns about risks of gastric cancer and carcinoid tumours, as well as parietal cell hyperplasia, colonic adenomas, and adenocarcinoma. Hypergastrinaemia and cell hyperplasia leading to carcinoid has been observed in rats [55] and in humans but these changes have not led to carcinoids [47]. Studies have shown gastrin levels to return to normal within one week of stopping treatment [55].

While the above-mentioned adverse effects are serious they are rare and importantly most of the adverse effects reported in literature relate to longer-term treatment. Solox Relief packaging is explicit in stating that the consumers should only use this medication for short (12 days) duration and if symptoms persist medical advice should be sought.

6. Contraindications.

Contraindications are listed on the medicine data sheet and will also be detailed in the package insert.

7. Possible resistance.

We do not anticipate any resistance to this reclassification.

8. Adverse events.

Lansoprazole has been used extensively worldwide and has an excellent safety record. It has highly specific activity, rapid clearance and is a weak base that is converted to the active form under acidic conditions.

A low incidence of events has been reported during clinical trials in 7,867 patients treated with lansoprazole. These events, which are generally transient and self-limiting, include headache, diarrhoea, abdominal pain,

dyspepsia, nausea, vomiting, dizziness, constipation, flatulence, rash, upper respiratory tract infections, urinary tract infections, arthralgia and myalgia.

Dermatological reactions include urticaria and pruritus. These generally resolve on discontinuation of drug therapy. Serious dermatological reactions are rare but there have been occasional reports of erythematous or bullous rashes including erythema multiforme.

Cases of hair thinning and photosensitivity have also been reported. Other reported reactions include jaundice, hepatitis, interstitial nephritis (sometimes resulting in renal failure), anaphylaxis, wheezing, angioedema, bruising, purpura, petechiae, depression, peripheral oedema, paraesthesia, blurred vision, taste disturbances, vertigo, confusion and hallucinations. Gynaecomastia and impotence may occur with long-term use.

During clinical trials a small number of patients developed abnormal liver function tests (predominantly gamma-GT) while on lansoprazole, however, routine monitoring of liver function tests is not required.

Isolated cases of blood dyscrasias, such as thrombocytopenia, leukopenia, neutropenia, agranulocytosis and pancytopenia have been reported, but a definite relationship to lansoprazole therapy has not been established.

9. Potential for abuse or misuse.

Lansoprazole has no known potential for abuse. The reclassification of Solox Relief to Pharmacist Medicine is not expected to increase the potential for abuse or misuse.

One important concern is the masking of gastric cancer with lansoprazole treatment. According to the British Society of Gastroenterology Dyspepsia Management Guidelines [23] the majority of patients with gastric cancer will present with characteristic symptoms (dysphagia, weight loss).

As Solox Relief is only a 12-day regimen, the short delay is unlikely to affect prognosis of a more serious condition. Most of the known serious adverse effects are related to longer term use, therefore a statement that consumers should use this medicine for a maximum of 12 days and if no relief is gained to seek further medical advice is detailed on the package/package insert. Combined with the proposed education campaign, we believe there is little to no potential for abuse.

While there are large numbers of people with dyspepsia and heartburn who self-medicate and do not seek medical advice, it could be perceived that there is a potential risk of prolonged use of lansoprazole OTC. However, with the packaging clearly stating that Solox Relief be only used for short-term treatment of symptoms (and with Pharmacist assurance and education) this risk would be minimised and would in fact be lower than that of other OTC acid reflux/ indigestion medications.

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