



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

Secretariat: Denise Tringham
PO Box 22 234
Wellington 6441
Tel: (04) 938 4827
Fax: (04) 976 4827
Email: denise@paediatrics.org.nz
Website: www.paediatrics.org.nz

Medicines Classification Committee
Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6145

18 September 2014

Dear Sir/Madam,

Submission to Medicines Classification Committee: 6.2 Omeprazole – proposed reclassification from pharmacy-only medicine to general sale medicine (Losec®, Bayer New Zealand Limited)

On behalf of the Pharmacists and Therapeutics Special Interest Group of the Paediatric Society of New Zealand, I would like to comment on the above submission.

This application seeks to make omeprazole more available with less input from a health professional. Some consumers of omeprazole are young children, who are therefore reliant on their caregivers to make diagnostic and treatment decisions.

The application is to have oral solid dosage forms of 10mg available as general sale and assumes that defining a list of indications and providing written usage instructions will result in safe use of omeprazole in all age groups. The risk is that making omeprazole 10mg capsules more easily available will increase exposure in a vulnerable population, which may increase the risk of misdiagnosis and incidence of adverse events. Monitoring of electrolytes should be part of any long term therapy with omeprazole and deranged electrolytes can have serious consequences in young children. We find omeprazole use can cause hyponatraemia and is often overused.

Omeprazole also can affect bone growth and development. Insoluble calcium requires an acidic environment for optimal absorption and PPI's remove that acidic environment. At CDHB we are limiting its use in our Children's Haematology and Oncology Centre and are asking prescribers to stop it when treatment with steroids have finished. We also have a problem with interactions with methotrexate and have one incident where a parent was going to give his own omeprazole to his child to settle his stomach whilst undergoing chemotherapy. We are concerned that if omeprazole was more easily available, interactions with other medicines would be missed.

We have outlined our concerns further by commenting on specific aspects of the application, and these comments are below.

'The proposed indication for Losec as a General Sales Medicine is:-

Short-term relief of gastric reflux-like symptoms that occur more than once a week, but not every day, in sufferers aged 18 years and over.' '.. This modified indication specifically restricts usage of the product to the appropriate patient population for over-the-counter omeprazole.'

Despite this comment on the packaging, there will be no restrictions on who checks this or how many packets are being purchased.

'Improved consumer choice of effective treatments - *the availability of omeprazole 10 mg as a General Sales Medicine will improve the choice of effective treatments available to consumers for self-selection at any outlet, particular for those that suffer symptoms more than one a week (but not every day).'*

The justification of increasing convenience for consumers is overstated, and should be seen in the context that it is being put forward by retailers whose true motivation is likely to be increased sales.

'Encourage Self-care – *reclassification of omeprazole 10 mg to General Sales Medicine would empower patients to independently address their health care needs for reflux/heartburn treatments.'*

Being able to purchase omeprazole in the supermarket will change the ease of access to omeprazole significantly for the paediatric population who are most vulnerable to inappropriate use.

'Consumer Convenience/Accessibility – *omeprazole at the lowest strength is suitable to be added to the range of products that can be self-selected at non-pharmacy type outlets, where more than 50% of remedies for reflux-like symptoms are currently purchased, offering consumers the opportunity to consider and compare at all points of purchase.'*

We are concerned that omeprazole 10mg capsules, if available via supermarkets, will be seen as a 'safe' option to purchase for children. Omeprazole has become a common choice for prescribers when choosing medicines for children with reflux. It is used in infants less than 1 year (the recommended age the medicine is registered for) on the advice of many clinical guidelines and paediatric texts. Community pharmacists are aware of the appropriate usage of omeprazole for this age group and are able to direct parents to seek further medical advice from their doctors if enquiring about purchasing omeprazole. Our concern is that parents may choose to self-medicate their children without seeking appropriate advice.

Comparison to H2 antagonists - *".....the safety and effectiveness of omeprazole is well documented, and that short term use of omeprazole has no additional risk compared to H2 antagonists currently available as general sale medicines.'*

Parents are unlikely to purchase H2 antagonists for children given the dose form. Children are prescribed ranitidine 150mg/10ml liquid which is not available via general sale. However, children are sometimes prescribed omeprazole 10mg capsules (the contents can be sprinkled onto soft food) once doses are at this level, so are more likely to purchase these if available via general sale.

Prolonged use

With up to 14 day's supply of omeprazole 10mg capsules in each packet, there is no guarantee that parents will seek medical advice before this. They may well purchase multiple boxes.

We have also attached links to two sources of information regarding the use of omeprazole in children. Please take note of the safety concerns with use of omeprazole as well as information regarding length of therapy. These are all things that will not be available when consumers purchase omeprazole via non-pharmacy outlets.

<http://www.cryingoverspiltmilk.co.nz/wp-content/uploads/2013/02/OmeprazoleSuspensionLetter.pdf>

<http://www.saferx.co.nz/full/Omeprazole.pdf>.

We are concerned that the information in the crying over spilt milk has some misinformation regarding splitting capsules for doses (inaccurate) and the risk of aspiration of the beads in very young children. Recently the Waitemata Neonatal Clinical Governance group has discussed this leaflet and contacted the author in regard to their concerns.

We oppose the classification of omeprazole to general sales due to safety concerns for the paediatric population.

We look forward to hearing from you soon with a response to our concerns.

Yours faithfully,



Louise McDermott
Chairperson,
Pharmacists and Therapeutics SIG
Paediatric Society of NZ

This letter is supported by members of the Pharmacist and Therapeutics Special Interest Group
Hannah Soper, Paediatric Pharmacist, Children's Haematology and Oncology Centre, CDHB
Rebecca Dean, Pharmacist ADHB
Kaajal Dijkstra, Pharmacist ADHB
Preetika Vareed, Pharmacist ADHB
Jenny Crawford, Pharmacist, Waitemata DHB