Health Canada Santé Canada

March 17, 2014

Notice

Our file number: 14-102848-660

Prescription Drug List (PDL): Omeprazole

The purpose of this Notice of Intent to Amend is to notify that, as a result of consultation, Health Canada will revise the listing for omeprazole on the Prescription Drug List (PDL). Only the Human part of the PDL is to be revised; the listing for Veterinary use will remain unchanged. Health Canada has conducted a scientific review of omeprazole against a set of established and publicly available criteria outlined in section C.01.040.3 of the *Food and Drug Regulations*. The wording, which remains unchanged from what was proposed in the November 5, 2013 Notice of Consultation, is:

Drugs containing the following:	Omeprazole or its salts *Oméprazole ou ses sels*
Including (but not limited to)	omeprazole, omeprazole magnesium *Oméprazole, l'oméprazole de magnesium*
Qualifier	except when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 milligram (mg) *sauf lorsque vendu pour un traitement d'une durée de 14 jours pour des brûlures d'estomac fréquentes, à une dose quotidienne de 20mg*
Effective Date	to be determined

Consultation summary:

Three comments were received with respect to the Notice for amending the PDL to grant nonprescription status for omeprazole or its salts when indicated for a 14-day treatment of frequent heartburn at daily dose of 20 mg. Two responses concurred with, while one expressed

…/2

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reservations about, this proposal, citing several scientific articles as well as public health advisories that have been issued by the United States Food and Drug Administration (FDA) and Health Canada regarding potential serious adverse drug reactions that may be associated with the use of proton pump inhibitors.

The serious adverse reactions that may be associated with the use of proton pump inhibitors, such as an increased risk of osteoporosis, bone fracture, C. difficile infections and, possibly, hypomagnesaemia and Vitamin B12 deficiency, usually are reported only after long-term (at least one year) daily use and/or with higher daily doses. Serious acute adverse drug reactions are very rare and rebound acid hypersecretion generally is not observed under the proposed conditions for nonprescription use.

The respondent noted that consumers may not heed product labelling that will restrict the use of daily 20 mg omeprazole to a two week regimen to be repeated only every 4 months. Omeprazole has an extensive history of safe use as a nonprescription medication in several countries which have adverse drug reaction reporting systems similar to that in Canada. Nonprescription omeprazole is available for the same indication, daily dose and duration of use in the United States (since 2003), the United Kingdom (2 x 10 mg tablets per day, since 2003), and Sweden (10 and 20 mg omeprazole, since 1999).

Data submitted in support of the proposed nonprescription status demonstrate that the use of omeprazole 20 mg for 14 days provides frequent heartburn sufferers with sustained relief from both daytime and nocturnal heartburn and is associated with an adverse event profile comparable to that of the placebo treated subjects. Label comprehension and actual use studies indicate that the majority of consumers understand the warnings, precautions and directions for use on the product labeling, as well as the circumstances under which use of omeprazole would be, or would not be, appropriate for them. The risks associated with the use of omeprazole, in terms of potential delays in seeking medical attention, are the same as those for other currently available nonprescription heartburn medications.

Issues pertaining to potential off-label use [that is (i.e.), the consumer increases the dosage and/or the duration of treatment beyond what is being proposed] and inability of the consumer to properly self-diagnose the condition for which nonprescription use of omeprazole is being proposed were addressed during the premarket review. On the basis of the data submitted (clinical trials, label comprehension and actual use studies), the overall benefit-to-risk is deemed acceptable for omeprazole under the proposed conditions of nonprescription use. Product labelling will be explicit and detailed with respect to the following important factors:

- clear description of what is meant by frequent heartburn;
- limiting the maximum daily dose to 20 mg omeprazole base;

…/3

- clear directions not to exceed 14 days of consecutive use, with no repeats until 4 months have elapsed.

The labeling will emphasize the fact that omeprazole is not to be used by individuals experiencing only occasional mild heartburn and that omeprazole is not the drug of choice for short-term hyperacidity problems since it takes several days to reach its optimum effect. The labeling also will include advice regarding lifestyle changes, such as avoiding heavy and/or very spicy meals, especially 2-3 hours before bedtime, minimizing alcohol and caffeine intake, stopping smoking, losing weight, etc. which help to ameliorate the condition. In addition, consumers will be advised to seek medical advice prior to beginning omeprazole if they are taking drugs whose safety and efficacy may be affected by omeprazole, such as clopidogrel.

Potential for interactions between omeprazole and several other commonly used medications will be listed on the consumer package insert.

Health Canada does not control the point of sale of nonprescription drugs (i.e. behind-the-counter or self-selection areas of a pharmacy). This is the responsibility of Provincial Pharmacy Regulatory Authorities (NAPRA) which base their decisions upon the recommendations of the National Drug Scheduling Advisory Committee (NDSAC).

Based on the results of this consultation, the Minister of Health intends to revise the listing for omeprazole or its salts when indicated for a 14-day treatment of frequent heartburn at daily dose of 20 mg. This revision will be in effect six months from the date of this Notice and communicated through a Notice of Amendment posted on the Health Canada website.

Should you have any questions on this update to the Prescription Drug List, please contact:

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