Addition of warning statements on labels of OTC oral and topical diclofenac medicines

Background

New Zealand is one of very few countries where diclofenac can be obtained over-the-counter. Currently there are no warning statements required under regulation 13(1)(i) of the Medicines Regulations 1984 to be placed on the label of over-the-counter medicines that contain diclofenac.

Diclofenac is a member of the class of non-steroidal anti-inflammatory drugs (NSAIDS). Warning statements are mandated for ibuprofen, which is a member of this class. Concerns have been raised recently over the cardiovascular safety of NSAIDS, particularly diclofenac.

The Medicines Adverse Reactions Committee (MARC) conducted a review on the safety of diclofenac and concluded that the safety information should be updated to include a warning about cardiovascular risk (http://www.medsafe.govt.nz/profs/adverse/Minutes154.htm).

The Australian Therapeutic Goods Administration (TGA) has also conducted a safety review of diclofenac (http://www.tga.gov.au/safety-review-diclofenac). The review established that excessive or prolonged continuous use of diclofenac increases the risk of heart attack or stroke, and the risk of liver damage. Prolonged or excessive use of topical diclofenac increases the potential for systemic absorption to occur.

In order to manage these risks, Medsafe proposes the following warning and advisory statements be included on the labels of OTC diclofenac medicines. Words of a similar meaning may be used.

Oral diclofenac

> Do not use if you are allergic to [name of active substance].
>
> Do not use if you are allergic to [other] anti-inflammatory medicines.
>
> If you get an allergic reaction, stop taking and see your doctor immediately.
>
> Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing other anti-inflammatory medicines or other medicines that you are taking regularly.
>
> Do not use if you have asthma except on doctor's advice.
>
> Do not use for more than a few days at a time except on doctor’s advice.
>
> Do not use [this product/insert name of the product] during the first 6 months of pregnancy, except on doctor’s advice.
>
> Do not use at all during the last 3 months of pregnancy.

Do not take more than the maximum stated dose.

Do not use if you have kidney problems.

Do not use if you have heart problems.

Long term use can be harmful and increases the risk of heart attack, stroke or liver damage.

Topical diclofenac

Do not use if you are allergic to [name of active substance].

Do not use if you are allergic to [other] anti-inflammatory medicines.

If you get an allergic reaction, stop taking and see your doctor immediately.

Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing other anti-inflammatory medicines or other medicines that you are taking regularly.

Do not use for more than 14 days except on doctor's advice.

Diclofenac can get into the blood and may affect the heart or increase the risk of a stroke.

Medsafe notes that many OTC diclofenac medicines are also registered in Australia and their labels already include most of these proposed warning and advisory statements. The additional warning and advisory statements recognise the risks identified from the safety review.

The current labels of approved OTC diclofenac medicines also include other warning and advisory statements that are not included in the above. These other statements do not have to be removed.

The target implementation date for the changes described above is 12 December 2015. This date is when Australia's Required Advisory Statements on Medicine Labels (RASML) No. 2 comes into effect.

As the majority of the OTC diclofenac medicines available in New Zealand are also registered in Australia, Medsafe is of the view that the target date for implementation can be met by product sponsors. Sponsors who think they may not be able to meet the proposed target date are invited to contact Medsafe with a justification and an alternative time line for implementation.

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