



Notice

Our file number: 14-102347-97

Prescription Drug List (PDL): Diclofenac

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 diclofenac 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 diclofenac 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 any of the following: Diclofenac or its salts
Diclofénac ou ses sels

Including (but not limited to) Diclofenac diethylamine, Diclofenac sodium,
Diclofenac potassium
Diclofénac diéthylamine, Diclofénac sodique, Diclofénac potassique

Qualifier except when sold as a single medicinal ingredient for topical use on the skin in a concentration equivalent to 2% or less of diclofenac for not more than 7 days.
sauf s'ils sont vendus comme ingrédient médicinal unique à une concentration équivalente à 2% ou moins de diclofénac dans les préparations pour usage topique sur une période de moins de 7 jours.

Effective Date 6 months from date of this Notice

Consultation summary:

The proposal to amend the PDL was communicated to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations through a Notice of Consultation posted on Health Canada's website on November 5, 2013. The 75 day consultation period which ended January 19, 2014 has been completed.

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Only two comments were received and both were favourable. Based on the results of this consultation, the Minister of Health intends to revise the listing for diclofenac by increasing the concentration from 1% to 2% for human non-prescription use. This revision will be in effect six months from the date of this Notice 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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