Health Canada Santé Canada

February 20, 2014

Notice

Our file number: 14-102089-470

Prescription Drug List (PDL): Hydrocortisone

The purpose of this Notice of Consultation is to provide an opportunity to comment on the proposal to revise the listing for hydrocortisone on the Prescription Drug List (PDL). Only the Human part of the PDL is proposed to be revised. The proposed wording of the new listing is:

Drugs containing any of the following:	Adrenocortical hormones or their salts or derivatives *Hormones corticosurrénales ou leurs sels ou dérivés*
Including (but not limited to)	hydrocortisone, hydrocortisone acetate, hydrocortisone valerate, hydrocortisone sodium succinate and clobetasone butyrate *l'hydrocortisone, acétate d'hydrocortisone, valérate d'hydrocortisone, hydrocortisone succinate de sodium et butyrate de clobétasone*
Qualifier	Except: (a) hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 1.0% or less hydrocortisone in preparations for topical use on the skin; or, (b) hydrocortisone or hydrocortisone acetate, when sold in combination with any other nonprescription medicinal ingredient that provides 1.0% or less hydrocortisone in preparations for topical use on the skin; or, (c) clobetasone butyrate when sold in a concentration of 0.05% in cream preparations for topical use on the skin. *Sauf :*

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	(a) l'hydrocortisone ou l'acétate d'hydrocortisone, vendu en tant qu'un ingrédient médicinal unique ou en combinaison avec d'autres ingrédients médicaux en ventre libre dont la concentration permet un apport de 1,0% ou moins d'hydrocortisone dans les préparations pour usage topique sur la peau; ou, *(b) hydrocortisone ou l'acétate d'hydrocortisone, vendu en combinaison avec n'importe quels autres ingrédients médicaux en vente libre dont la concentration permet un apport de 1,0 % ou moins d'hydrocortisone dans les préparations pour usage topique sur la peau; ou,* *(c) le butyrate de clobétasone vendu sous forme de crème contenant 0,05 % pour usage topique sur la peau.*
Effective Date	to be determined

Rationale:

Use of topical hydrocortisone, as the hydrocortisone base or as an acetate salt, at a concentration of .5% as a single ingredient drug product has been a nonprescription product for more than 25 years. Evidence has been assessed by Health Canada that indicates that topical 1% hydrocortisone either as a single medicinal ingredient or when mixed with other nonprescription medicinal ingredients can be safely used in the nonprescription setting. The main concern with increasing the dose hydrocortisone is the possibility of increased systemic absorption which may affect other areas of the body not intended by the topical application. A review conducted by the United States Food and Drug Administration in 1990 indicated that even levels of 2.5% hydrocortisone did not increase systemic absorption significantly. Local adverse effects such as striae formation, telangiectasia or infection were not seen at the 1 % concentration. Prescription products containing 1% hydrocortisone rarely had adverse reactions reported and none were serious.

The addition of other nonprescription medicinal ingredients such as urea, zinc sulfate or pramoxine is not expected to increase percutaneous absorption of hydrocortisone nor increase adverse events.

In conclusion, none of the criteria outlined in section C.01.040.3 of the Food and Drug Regulations apply to hydrocortisone when sold for human use as a single medicinal ingredient or in mixtures with other nonprescription ingredients in preparations for topical use on the skin in a concentration equivalent to 1% or less of hydrocortisone.

Additional information on how Health Canada determines prescription status (or nonprescription status) is available in the *Guidance Document: Determining Prescription Status for Human and Veterinary Drugs* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_gd_ord_ld-eng.php).

Currently six Drug Identification Number (DIN) products containing hydrocortisone or hydrocortisone acetate as a single medicinal ingredient and thirteen DIN products in combination with other nonprescription medicinal ingredients are affected by this proposal. If the proposal is accepted these products will need to transition to the *Natural Health Product Regulations*. DIN holders will be given six months after the posting a Notice of Intent to Amend for this transition.

Comments on this proposed change to the Prescription Drug List should be provided to Health Canada, preferably in electronic format, within 75 days from the date of this notice.

Please send your comments to:

Health Canada
Prescription Drug Status Committee
Address Locator 3102C3
Holland Cross, Tower B
1600 Scott Street
Ottawa, Ontario
K1A 0K9

Telephone: 613-957-1058
Facsimile: 613-941-5035

E-mail: drug_prescription_status-statut_d'ordonnance_des_drogues@hc-sc.gc.ca

If all comments not in favour of this change can be addressed, a Notice of Intent to Amend will be posted on the Health Canada website. This Notice will address these comments and inform stakeholders of Health Canada's intention to revise the PDL. The actual revision to the PDL would be made six months from the date of the Notice of Intent to Amend and communicated to stakeholders through a Notice of Amendment.