Health Canada Santé Canada

March 17, 2014

Notice

Our file number: 14-102787-565

Prescription Drug List (PDL): Triamcinolone acetonide

The purpose of this Notice of Consultation is to provide an opportunity to comment on the proposal to revise the listing for Adrenocortical hormones on the Prescription Drug List (PDL). Only the human part of the PDL is proposed to be revised; the listing for Adrenocortical hormones for Veterinary use will remain unchanged. The proposed wording of the new listing is:

Drugs containing 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, Clobetasone butyrate, Difluprednate, Triamcinolone acetonide *l'hydrocortisone, acétate d'hydrocortisone, valérate d'hydrocortisone, hydrocortisone succinate de sodium, butyrate de clobétasone, difluprednate et acétonide de triamcinolone*
Qualifier	Triamcinolone acetonide in a nasal spray that delivers 55 microgram (mcg)/spray for those 12 years of age and older. *Acétonide de triamcinolone administrée par vaporisation nasale, à raison d'une dose de 55 mcg/jet, destinée à des personnes âgées de 12 ans ou plus.*
Effective Date	to be determined

Rationale:

Triamcinolone acetonide (TAA) was approved and first marketed in Canada in 1996 for the treatment of the symptoms of perennial allergic rhinitis (PAR) and seasonal allergic rhinitis (SAR) unresponsive to conventional treatment in adults and adolescents 12 years and older.

Prescription status for TAA was not based on the product's indication, but for safety concerns about chronic use of corticosteroids, even at the relatively low dose for intranasal use. Bioavailability from the nasal cavity is low such that systemic absorption is also low. Post-market experience indicates the use of

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TAA for the above indications shows no undesirable or severe side effects. Under the proposed nonprescription use it is not recommended for children under 12 years of age. It is also recommended that if the symptoms have not improved after a week of use, the user should see their doctor.

In conclusion, none of the criteria outlined in section C.01.040.3 of the *Food and Drug Regulations* apply to Triamcinolone acetonide when sold for human use for the treatment of PAR and SAR in a nasal spray that delivers 55 mcg/spray for those 12 years of age and older.

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).

Please send your comments to:

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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.