Notice: Prescription Drug List (PDL): Fluticasone propionate

November 27, 2015
Our file number: 15-112766-443

The purpose of this Notice of Consultation is to provide an opportunity to comment on the proposal to revise the listing for Adrenocortical Hormones or their salts or derivatives on the Human Prescription Drug List (PDL) to permit the non-prescription use of Fluticasone propionate for the conditions listed below. Only the human part of the PDL is proposed to be revised. The proposed qualifier for the listing on the Human List is:

**Drugs containing the following:** Adrenocortical hormones or their salts or derivatives

**Including (but not limited to):** Betamethasone valerate, betamethasone sodium, betamethasone phosphate, betamethasone dipropionate, budesonide, ciclesonide, clobetasone, cortisone, dexamethasone sodium, dexamethasone phosphate, dexamethasone acetate, difluprednate, fludrocortisone acetate, flunisolide, fluticasone propionate, fluticasone furoate, hydrocortisone acetate, hydrocortisone aceponate, hydrocortisone sodium, methylprednisolone acetate, methylprednisolone, methylprednisolone succinate, methylprednisolone sodium, mometasone furoate, prednisolone acetate, prednisolone sodium, prednisolone phosphate, prednisone, triamcinolone acetonide, triamcinolone hexacetonide

**Qualifier:** Fluticasone propionate for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older

**Effective Date:** to be determined

**Rationale:**

Health Canada has conducted a scientific assessment of this switch against a set of established and publicly available criteria outlined in section C.01.040.3 of the Food and Drug Regulations.

Additional information on how Health Canada determines prescription status (or non-prescription status) is available in the *Guidance Document: Determining Prescription Status for Human and Veterinary Drugs*.

Fluticasone propionate aqueous nasal spray (50 mcg/metered spray) was approved and first marketed in Canada in 1993 for the treatment of the symptoms associated with seasonal allergic rhinitis including hay fever and perennial rhinitis. Regular usage is essential for full therapeutic benefit since maximum relief may not be obtained until after 2 to 3 days of treatment.

Allergic rhinitis is easily self-identifiable by consumers. The usual symptoms are sneezing, itchy and runny nose, itchy eyes, and nasal congestion that are readily diagnosed, treated and monitored by the consumer. Consumer Behaviour Studies provided to support the use of fluticasone propionate in the OTC setting for consumers 18 years and older were adequate. The Label Comprehension Studies provided corroborated this finding by demonstrating that consumers over 18 years of age were able to appropriately self-select and medicate according to the labeled directions. They are instructed to consult a doctor if symptoms do not improve or get worse after 7 days or after three month of continual use.

The indication statement for FLONASE® Allergy Relief is similar to the two other corticosteroids for nasal use for the treatment of symptoms of allergic rhinitis which were recently switched: NASACORT® Allergy 24HR (triamcinolone acetonide nasal spray) and NASONEX Allergy and Congestion (mometasone furoate monohydrate nasal spray).

Comments on this proposed change to the Prescription Drug List should be provided to Health Canada in writing, 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: 613-941-1812
E-mail: drug_prescription_status-statut_d'ordonnance_des_droghes@hc-sc.gc.ca

If all comments not in favour of this switch 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.

Date Modified: 2015-11-27