Patients' Information

রোগীদের জন্য তথ্য

Flonasin™

Azelastine Hydrochloride and Fluticasone Propionate

COMPOSITION

Flonasin™ Nasal Spray: Each metered spray delivers Azelastine Hydrochloride BP 137 mcg and Fluticasone Propionate BP 50 mcg.

PHARMACOLOGY

Azelastine Hydrochloride exhibits histamine H1-receptor antagonist activity in isolated tissues. The major metabolite, desmethylazelastine, also possesses H1-receptor antagonist activity. Fluticasone Propionate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. The precise mechanism through which Fluticasone Propionate affects allergic rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes etc.) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation.

INDICATION

Flonasin™ Nasal Spray is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 6 years of age and older who require treatment with both Azelastine Hydrochloride and Fluticasone Propionate for symptomatic relief.

CONTRAINDICATION

There is no known contraindication.

DOSAGE AND ADMINISTRATION

The recommended dosage is one spray each nostril twice daily.

PRECAUTION

Engagement in hazardous occupations requiring complete mental alertness such as driving or operating machinery should be avoided when taking **Flonasin**™ Nasal Spray. Concurrent use of alcohol or other central nervous system (CNS) depressants with this Nasal Spray should also be avoided because of further decreased alertness and impairment of CNS. Hypercorticism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals may appear. If such changes occur, the spray should be discontinued slowly.

SIDE EFFECT

The most common adverse reactions (≥2% incidence) are: dysgeusia, epistaxis, and headache.

SPECIAL POPULATION

Use in Pregnancy: Pregnancy category C. There are no adequate and well-controlled clinical trials of Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray, Azelastine Hydrochloride only or Fluticasone Propionate only in pregnant women. It should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when administered to a nursing woman.

Paediatric use: The safety and effectiveness of Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray has not been established for patients less than 6 years of age.

OVERDOSE

There have been no reported over dosages with Azelastine Hydrochloride. Acute Azelastine Hydrochloride overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence. Chronic Fluticasone Propionate overdosage may result in symptoms of hypercorticism.

STORAGE

Store below 25^0 C. Protected from light. Do not store in the refrigerator. Keep out of the reach of children.

HOW SUPPLIED

Flonasin™ Nasal Spray: Each bottle contains aqueous suspension of Azelastine Hydrochloride and Fluticasone Propionate adequate for 120 metered sprays.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh

TM-Trade Mark