

PRESCRIBING INFORMATION

DUONASE Nasal Spray

Composition

Each spray delivers

Azelastine hydrochloride 140 mcg

Fluticasone propionate 50 mcg

Description

Duonase is an antihistamine-corticosteroid combination available as a metered spray formulation for intranasal administration. It contains azelastine hydrochloride, which is a second generation H₁ receptor antagonist with potent topical activity and fluticasone propionate, a synthetic corticosteroid with anti-inflammatory properties.

Indications

Duonase is indicated for the management of symptoms of allergic rhinitis once the need for an antihistamine and corticosteroid has been established. It is recommended to treat **moderate to severe persistent symptoms** in adults above 12 years. For children above 5 years **Duonase** is recommended for **severe symptoms** of allergic rhinitis. **Duonase** can also be used for treating non-allergic vasomotor rhinitis in adults and children 12 years of age and older.

Dosage and administration

Adults and children 5 years and older: 1 spray/nostril twice daily

The recommended dosage should not be exceeded. Not recommended for use in children below 5 years.

Contraindications

Duonase is contraindicated in patients with or known hypersensitivity to azelastine hydrochloride or fluticasone propionate or any of the components of the preparation.



Warnings and Precautions

- Concurrent use of this combination with alcohol or other CNS depressants or other antihistamines should be avoided as additional reductions in alertness and additional impairment of CNS performance may occur due to azelastine.
- The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal e.g. joint and/or muscular pain, lassitude and depression.
- The concomitant use of an intranasal corticosteroid with other corticosteroids could increase the risk of signs or symptoms of hypercorticism and/ or suppression of the HPA-axis. Therefore the combination should be used cautiously in patients with other pathological conditions requiring steroids.
- Intranasal corticosteroids may cause a reduction in growth velocity when administered at higher dose. The recommended dosage of **Duonase** should not be exceeded.
- Special care is needed in patients with lung tuberculosis and fungal and viral infections. Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles for example can have a more serious or even a fatal course in children on immunosuppressant corticosteroids.
- During long term therapy, monitoring of hematological and adrenal function is advisable.
- In clinical studies with intranasal fluticasone propionate, the development of localized infections of the nose and the pharynx with *Candida albicans* has been seen rarely. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of the treatment with **Duonase** is advised

DRUG INTERACTIONS

The use of **Duonase** in patients taking concurrent drugs, which are potent inhibitors of the cytochrome 450 3A4 system eg. Ketoconazole and protease inhibitors such as ritonavir may be associated with increased systemic exposure of fluticasone.

PREGNANCY

The combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

LACTATION

It is not known whether azelastine hydrochloride or fluticasone propionate is excreted in human milk. Hence, caution should be exercised while prescribing this combination to nursing mothers.

Side Effects

The most likely side effects with this combination are headache, somnolence, pharyngitis, epistaxis, nasal burning/irritation, nausea, vomiting, cough, taste disturbance. The combination may produce a bitter taste, which may lead to occasional nausea. Bitter taste disappears after sometime.

Presentation

Duonase Nasal Spray

Sales pack contains 70-metered doses