

ZALASTIN Nasal Spray

For medical
professionals
only

Composition:

Each 1 ml contains:

Azelastine hydrochloride.....1 mg.

Properties:

Azelastine HCl is a second generation antihistamine characterized by a rapid onset and a long duration of action. It inhibits the release of inflammatory mediators of mast cells.

Indications:

ZALASTIN Nasal Spray is indicated for the treatment of symptoms of seasonal or perennial allergic rhinitis such as rhinorrhea, sneezing and nasal pruritus in adults and children 5 years and older.

Dosage:

- The recommended dose of **ZALASTIN** Nasal Spray is:

Adults and children 12 years and older: two sprays (140 ug/spray) per nostril twice daily.

Children 5-11 years old: one spray per nostril twice daily.

- Before initial use, the unit should be primed with 4 sprays or until a fine mist appears. If it is not used for more than 3 days, the unit should be reprimed with 2 sprays or until a fine mist appears.

- Before using the nasal spray, the nasal passages should be cleared. Close one nostril, press and sniff deeply and breath out through your mouth.

Adverse Effects:

Irritation of nasal mucosa, bitter taste, drowsiness, tiredness, dry mouth, skin rash, abdominal pain or anorexia may occur.

Contraindications:

Azelastine hydrochloride is contraindicated in patients with known hypersensitivity to azelastine hydrochloride.

Precautions:

- *Activities requiring mental alertness:* Somnolence has been reported in some patients taking azelastine hydrochloride; caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

- *Pregnancy:* There are no adequate and well-controlled clinical studies in pregnant women. Azelastine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

- *Nursing mothers:* It is not known whether azelastine hydrochloride is excreted in human milk; caution should be exercised when azelastine hydrochloride is administered to a nursing woman.

- *Pediatric use:* Safety and efficacy of azelastine hydrochloride in pediatric patients below the age of 5 years have not been established.

Drug Interactions:

Concurrent use of azelastine hydrochloride with alcohol or other CNS depressants should be avoided because additional reduction in alertness and additional impairment of CNS performance may occur.

Pack:

A bottle containing 15 ml (100 metered dose).