

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information
Fluticasone Furoate and Azelastine Hydrochloride Nasal Spray
Allegra® nasal Duo

Each actuation delivers: Fluticasone Furoate 27.5 mcg and Azelastine Hydrochloride I.P. 140 mcg

COMPOSITION:

Fluticasone Furoate 0.0275%w/w, Azelastine Hydrochloride I.P. 0.140% w/w, Benzalkonium Chloride I.P. 0.01 % w/w (as preservative), Excipients q.s.

INDICATIONS: It is indicated for the treatment of symptoms of allergic rhinitis. It is indicated for the management of symptoms of allergic rhinitis, once the need for an antihistamine and corticosteroid has been established. It is recommended for the treatment of persistent, moderate to severe symptoms in adults and adolescents above 12 years of age.

DOSAGE AND ADMINISTRATION: Allegra® nasal Duo should be administered by the intranasal route only. Adults and Adolescents (12 years of age and older): One spray per nostril twice daily. The recommended dosage should not be exceeded. Shake the bottle well before each use.

For Intranasal use only. Do not spray in the mouth and eyes.

CONTRAINDICATIONS: Allegra® nasal Duo is contraindicated in patients with known hypersensitivity to fluticasone furoate or azelastine hydrochloride or any of the components of this preparation.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Fluticasone Furoate: Do not co-administer with ritonavir because of the potential risk of increased systemic exposure to Fluticasone Furoate. A reduction in growth has been observed in children treated with fluticasone furoate. When administered with other intranasal corticosteroids risk of ocular changes such as central serous chorioretinopathy persist.

Azelastine Hydrochloride: Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness and motor coordination such as operating machinery or driving a motor vehicle after administration of Azelastine Hydrochloride. Concurrent use of Azelastine Hydrochloride with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur.

PREGNANCY AND LACTATION: Allegra® nasal Duo should not be used in pregnancy or lactation, unless advised by the physician.

ADVERSE REACTIONS: *Fluticasone furoate* - becoming very wheezy, coughing or having difficulty with breathing, suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness), swelling around the face, skin rashes or redness, headache, nosebleeds (generally minor), particularly if Fluticasone furoate is used for more than 6 weeks continuously, nasal ulceration – which may cause irritation or discomfort in the nose. Patient may also get streaks of blood when they blow their nose.

Azelastine Hydrochloride- Use of Azelastine Hydrochloride has been associated with somnolence.

For full prescribing information please contact: Sanofi India Limited, Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

Created: Feb 2022

Source: Allegra nasal DUO prescribing information dated Feb 2022