

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)

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.**

SAFETY RELATED INFORMATION

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. Systemic effects of nasal corticosteroid have been reported, particularly at high doses prescribed for prolonged periods. 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 only be considered if the expected benefit to the mother is greater than any possible risk to the child.

ADVERSE REACTIONS: *Fluticasone furoate* - Epistaxis, Nasal ulceration, dyspnoea, Headache
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

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