Abridged Prescribing Information

Allegra[®] nasal Fluticasone Furoate Nasal Spray

Each actuation delivers: Fluticasone Furoate - 27.5 mcg.

Composition: Fluticasone Furoate - 0.055%w/w; Benzalkonium Chloride I.P. - 0.015 % w/w (Added as preservative)

Indications: Allegra[®] nasal is indicated for the treatment of symptoms of allergic rhinitis.

Dosage and Administration: For Adults and adolescents 12 years and over 110mcg (two sprays in each nostril) once daily. For Children 2 to 11 years of age, 55mcg (one spray in each nostril) once daily. Not recommended for children under 2 years of age. Do not exceed the prescribed dosage. Shake the bottle well before each use. For Intranasal use only. Do not spray in the mouth and eyes.

SAFETY-RELATED INFORMATION

Special Warnings and Precautions for Use: 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 Use of fluticasone furoate 110mcg daily for one year in children decreases their growth rate. Physicians should be alert to potential systemic steroid effects including ocular changes such as central serous chorioretinopathy.

Contraindications: Hypersensitivity to any of the ingredients.

Pregnancy and Lactation: Fluticasone Furoate should be used in pregnancy only if the benefits to the mother outweigh the potential risks to the foetus or child. The excretion of Fluticasone Furoate into human breast milk has not been investigated.

Adverse Reactions: Nasal ulceration, Epistaxis, and headache.

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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Source: Pack Insert of Allegra® nasal (Fluticasone Furoate nasal spray) dated Dec 2023