

Abridged Prescribing Information

Rx

Fluticasone Furoate Nasal Spray

Allegra® 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)

Excipientsq.s.

Indications:

Allegra® nasal spray 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

Special Warnings and Precautions for Use:

Do not co-administer with ritonavir because of the potential risk of increased systemic exposure to Fluticasone Furoate. Use of fluticasone furoate 110mcg daily for one year in children decreases their growth rate. When administered with other intranasal corticosteroids risk of ocular changes such as central serous chorioretinopathy persist. Risk of systemic corticosteroid side effects increases while using with potent inhibitors of CYP3A4.

Contraindications: Hypersensitivity to any of the ingredients in the formulation.

Pregnancy: Fluticasone Furoate should be used in pregnancy (pregnancy category C) only if the benefits to the mother outweigh the potential risks to the foetus or child.

Lactation: The excretion of Fluticasone Furoate into human breast milk has not been investigated.

Adverse Reactions: Nasal ulceration, Epistaxis, Pain in nose, nasal discomfort like nasal burning, nasal irritation and nasal soreness, nasal dryness 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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