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

This package insert is continually updated: Please read carefully before using a new pack

Fluticasone Furoate Nasal Spray
Allegra® nasal

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)
Excipients …….q.s.

DOSAGE FORM
Nasal spray, suspension.

INDICATIONS:
Allegra® nasal is indicated for the treatment of symptoms of allergic rhinitis.

DOSAGE AND ADMINISTRATION:
Adults and adolescents (12 years and older)
The recommended dosage is two sprays (27.5 mcg of fluticasone furoate per spray) in each nostril once daily (total daily dose, 110 mcg).
Once adequate control of symptoms is achieved, dose reduction to one spray actuation in each nostril once daily (total daily dose 55 micrograms) may be effective for maintenance.

Children (2 to 11 years of age)
The recommended starting dosage is one spray (27.5 mcg of fluticasone furoate per spray) in each nostril once daily (total daily dose, 55 mcg).
Patients not adequately responding to one spray in each nostril once daily (total daily dose, 55 mcg) may use two sprays in each nostril once daily (total daily dose, 110 mcg). Once adequate control of symptoms is achieved, dose reduction to one spray in each nostril once daily (total daily dose, 55mcg) is recommended.

Children under 2 years of age
There are no data to recommend use of **Allegra® nasal** for the treatment of allergic rhinitis in children under 2 years of age.

Elderly Patients
No dose adjustment is required in this population (*Refer Pharmacokinetic Properties*).

Renal Impairment
No dose adjustment is required in this population (*Refer Pharmacokinetic Properties*).

Hepatic Impairment
No dosage adjustment is required in patients with hepatic impairment. (*Refer Special Warnings and Precautions for Use and Pharmacokinetic Properties*).

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.

CONTRAINDICATIONS:
Allegra® nasal is contraindicated in patients with hypersensitivity to any of the ingredients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Based on data with another glucocorticoid metabolized by CYP3A4, co-administration with ritonavir is not recommended because of the potential risk of increased systemic exposure to fluticasone furoate *(Refer Drug Interaction and Pharmacokinetic Properties).*

Systemic effects of nasal corticosteroid have been reported, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

A reduction in growth velocity has been observed in children treated with fluticasone furoate 110mcg daily for one year *(Refer adverse reactions)* Therefore, children should be maintained on the lowest dose which delivers adequate symptom control (*Refer dosage and administration).*

As with other intranasal corticosteroids, physicians should be alert to potential systemic steroid effects including ocular changes such as central serous chorioretinopathy.

DRUG INTERACTION

Fluticasone Furoate is rapidly cleared by extensive first pass metabolism mediated by the cytochrome P450 3A4. Take caution while using intranasal Fluticasone Furoate with potent inhibitors of CYP3A4 like ketoconazole which may increase the risk of systemic corticosteroid side effects. In a drug interaction study of intranasal fluticasone furoate with the potent CYP3A4 inhibitor ketoconazole, there were more subjects with measurable fluticasone furoate plasma concentrations in the ketoconazole group (6 of the 20 subjects) compared to placebo (1 of the 20 subjects). This small increase in exposure did not result in a statistically significant difference in 24-hour serum cortisol levels between the two groups. The enzyme induction and inhibition data suggest that there is no theoretical basis for anticipating metabolic interactions between fluticasone furoate and the cytochrome P450 mediated metabolism of other compounds at clinically relevant intranasal doses.

Therefore, no clinical studies have been conducted to investigate interactions of fluticasone furoate on other drugs *(Refer Special Warnings and Precautions for use and Pharmacokinetic Properties).*

USE IN SPECIAL POPULATIONS (such as Pregnancy, Lactation and Fertility)

Pregnancy

Fluticasone Furoate should be used in pregnancy only if the benefits to the mother outweigh the potential risks to the foetus or child. Following intranasal administration at the maximum recommended human dose (110 micrograms/day), plasma fluticasone furoate concentrations were typically non-quantifiable and therefore potential for reproductive toxicity is expected to be very low.

Lactation

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

Fertility

There is no data in humans.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Based on the pharmacology of fluticasone furoate and other intranasally administered steroids, there is no reason to expect an effect on ability to drive or to operate machinery with **Allegra® nasal.**

ADVERSE REACTIONS:

The following convention has been used for the classification of frequency: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Clinical Trial Data

Respiratory, thoracic and mediastinal disorders:

Very Common: Epistaxis
Common: Nasal ulceration

Musculoskeletal and connective tissue disorder (Children)

Not known: Growth retardation

Post-Marketing Data

Immune system disorders:
Rare: Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria

Nervous system disorders:
Common: Headache

Respiratory, thoracic and mediastinal disorders:

Uncommon: Rhinalgia, nasal discomfort (including nasal burning, nasal irritation and nasal soreness), nasal dryness
Very rare: Nasal septum perforation

OVERDOSE:

Symptoms and Signs
Intranasal doses of up to 24 times the recommended daily adult dose were given over three days with no adverse systemic effects.

Treatment
Acute overdose is unlikely to require any therapy other than observation.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties:

Mechanism of Action:
Fluticasone furoate is a synthetic trifluorinated corticosteroid that possesses a very high affinity for the glucocorticoid receptor and has a potent anti-inflammatory action.

Pharmacokinetics Properties:
Absorption
Fluticasone furoate undergoes incomplete absorption and extensive first-pass metabolism in the liver and gut resulting in negligible systemic exposure. The intranasal dosing of 110 micrograms once daily does not typically result in measurable plasma concentrations (less than 10 picograms /mL). The absolute bioavailability for fluticasone furoate administered as 880 micrograms three times per day (2640 micrograms total daily dose) is 0.50%.

Distribution
The plasma protein binding of fluticasone furoate is greater than 99 %. Fluticasone Furoate is widely distributed with volume of distribution at steady-state of, on average, 608 L.

Metabolism
Fluticasone furoate is rapidly cleared (total plasma clearance of 58.7 L/h) from systemic circulation principally by hepatic metabolism to an inactive 17 beta-carboxylic metabolite (GW694301X), by the cytochrome P450 enzyme CYP3A4. The principal route of metabolism was hydrolysis of the S-fluoromethyl carbothioate function to form the 17β-carboxylic acid metabolite.
In vivo studies have revealed no evidence of cleavage of the furoate moiety to form fluticasone.

Elimination
Elimination was primarily via the faecal route following oral and intravenous administration indicative of excretion of fluticasone furoate and its metabolites via the bile. Following intravenous administration, the elimination phase half-life averaged 15.1 hours. Urinary excretion accounted for approximately 1 % and 2 % of the orally and intravenously administered dose, respectively.

Special Patient Populations

Elderly
Only a small number of elderly subjects (n=23/872; 2.6%) provided pharmacokinetic data.
There was no evidence for a higher incidence of subjects with quantifiable Fluticasone Furoate concentrations in the elderly, when compared to the younger subjects.

Children
Fluticasone Furoate is typically not quantifiable (less than 10 picograms /mL) following intranasal dosing of 110 micrograms once daily. Quantifiable levels were observed in less than 16% of paediatric patients following intranasal dosing of 110 micrograms once daily and only less than 7% of paediatric patients following 55 micrograms once daily. There was no evidence for a higher incidence of quantifiable levels of fluticasone furoate in younger children (less than 6 years of age).

Renal impairment
Fluticasone furoate is not detectable in urine from healthy volunteers after intranasal dosing. Less than 1% of dose-related material is excreted in urine and therefore renal impairment would not be expected to affect the pharmacokinetics of fluticasone furoate.

Hepatic impairment
There are no data on intranasal fluticasone furoate in subjects with hepatic impairment. Data are available following inhaled administration of fluticasone furoate (as fluticasone furoate or fluticasone furoate/vilanterol) to subjects with hepatic impairment that are also applicable for intranasal dosing.

A study of a single 400 microgram dose of orally inhaled fluticasone furoate in patients with moderate hepatic impairment (Child-Pugh B) resulted in increased C_{max} (42%) and AUC (0-∞) (172%) compared to healthy subjects. Following repeat dosing of orally inhaled Fluticasone Furoate /vilanterol for 7 days, there was an increase in fluticasone furoate systemic exposure (on average two-fold as measured by
$AUC_{(0–24)}$) in subjects with moderate or severe hepatic impairment (Child-Pugh B or C) compared with healthy subjects. The increase in fluticasone furoate systemic exposure in subjects with moderate hepatic impairment (fluticasone furoate /vilanterol 200/25 micrograms) was associated with an average 34% reduction in serum cortisol compared with healthy subjects. There was no effect on serum cortisol in subjects with severe hepatic impairment (fluticasone furoate /vilanterol 100/12.5 micrograms). Based on these findings the average predicted exposure for 110 micrograms of intranasal fluticasone furoate in this patient population would not be expected to result in suppression of cortisol.

Other pharmacokinetics
Fluticasone furoate is typically not quantifiable (less than 10 picograms/mL) following intranasal dosing of 110 micrograms once daily. Quantifiable levels were only observed in less than 31% of patients aged 12 years and above and in less than 16% of paediatric patients following intranasal dosing of 110 micrograms once daily. There was no evidence for gender, age (including paediatrics), or race to be related to those subjects with quantifiable levels, when compared to those without.

PRESENTATION: 6 g /120 Metered doses

STORAGE INSTRUCTIONS: Store at temperature below 30^0C, Protect from light. Do not freeze.
Keep the medicines out of reach of children.

Manufactured in India by: M/s Biodeal Pharmaceuticals Ltd., Vill.: Sainimajra, Nalagarh - Ropar Road, Nalagarh - 174101, Distt. Solan , (H.P), India.

Marketed by: Sanofi Consumer Healthcare India Limited, Unit 1104, 11th Floor, Godrej Two, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400079, Maharashtra
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Steps to use your nasal spray correctly

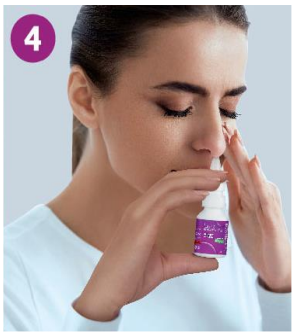
Parts of the Nasal Spray

STEP 1
Blow your nose gently.

STEP 2
Shake the bottle gently and then remove the protective dust cap.
Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.

STEP 3
If using for the first time or if you have not used it for a week or more, test the spray.
Testing of the spray: With the nozzle pointing away from you, press down a few times as shown until a fine mist comes out of the nozzle.

STEP 4
Close one nostril and hold the bottle as shown in step 2.
Tilt your head forward slightly and keeping the bottle upright, carefully insert the tip of the nozzle in the other nostril.



STEP 5
Start to breathe in through your nose and while breathing in, press down with your fingers once to release a spray.

STEP 6
Breathe out through your mouth. Repeat steps 5 and 6 to inhale a second spray.

STEP 7
Repeat steps 4,5 and 6 for the other nostril.

STEP 8
Wipe the nozzle with a clean handkerchief/ tissue and replace the protective dust cap.

IMPORTANT POINTS TO NOTE WHILE USING THE NASAL SPRAY

- Remove cap.
- DO NOT pierce the nozzle to use the nasal spray.

- If using for the first time or after storage for many days, please firmly press the nozzle at least 4-6 times to activate the spray.
- For effective use of the nasal spray, PRESS DOWN THE FINGER FLANGE DISC COMPLETELY. Incomplete or partial press will not release the medicine.