For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name

Fluticasone Furoate Nasal Spray

Solspre® F Mist

2. Qualitative and Quantitative Composition:

Each Spray delivers:
Fluticasone Furoate EP……..…27.5 mcg
Composition:
Fluticasone Furoate EP……0.055% w/w
Excipients……q.s.
Preservatives:
Benzalkonium Chloride I.P….0.015% w/w

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of symptoms of allergic rhinitis.

4.2 Posology and method of administration

Posology

Administer SOLSPRE F MIST nasal spray by the intranasal route only.

- Before using SOLSPRE F MIST nasal spray for the first time, shake well and release 6 sprays into the air away from the face.
- When SOLSPRE F MIST nasal spray has not been used for more than 30 days or if the cap has been left off the bottle for 5 days or longer, prime the pump again until a fine mist appears.
- Shake SOLSPRE F MIST nasal spray well before each use.
- Titrate an individual patient to the minimum effective dosage to reduce the possibility of side effects.

Adults and Adolescents Aged 12 Years and Older

The recommended starting dosage is 110 mcg once daily administered as 2 sprays (27.5 mcg/spray) in each nostril. When the maximum benefit has been achieved and symptoms have been controlled, reducing the dosage to 55 mcg (1 spray in each nostril) once daily may be effective in maintaining control of allergic rhinitis symptoms.

Children Aged 2 to 11 Years

The recommended starting dosage in children is 55 mcg once daily administered as 1 spray (27.5 mcg/spray) in each nostril. Children not adequately responding to 55 mcg may use 110 mcg (2 sprays in each nostril) once daily. Once symptoms have been controlled, dosage reduction to 55 mcg once daily is recommended.

Method of Administration:

4.3 Contraindications

SOLSPRE F MIST nasal spray is contraindicated in patients with hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

For Nasal Use Only.

Epistaxis, nasal ulceration, Candida albicans infection, nasal septal perforation, impaired wound healing. Monitor patients periodically for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma.

- Development of glaucoma or posterior subcapsular cataracts. Monitor patients closely with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.
- Hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria, may occur after administration of SOLSPRE F MIST nasal spray.
- Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.
- More serious or even fatal course of chickenpox or measles in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections.
- Hypercorticism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue SOLSPRE F MIST nasal spray slowly.
- Potential reduction in growth velocity in children. Monitor growth routinely in pediatric patients receiving SOLSPRE F MIST nasal spray.
- KEEP SOLSPRE F MIST NASAL SPRAY OUT OF THE REACH OF CHILDREN.

4.5 Drug Interactions

Potent inhibitors of cytochrome P450 3A4 (CYP3A4) may increase exposure to fluticasone furoate.

- Co-administration of ritonavir is not recommended.

- Use caution with co-administration of other potent CYP3A4 inhibitors, such as ketoconazole.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)
SOLSPRE F MIST nasal spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Since there are no data from controlled trials on the use of intranasal fluticasone furoate by nursing mothers, caution should be exercised when SOLSPRE F MIST nasal spray is administered to a nursing woman.

4.7 Effects on ability to drive and use machines
It has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Systemic and local corticosteroid use may result in the following:

- Epistaxis, headache, pharyngo-laryngeal pain, back pain, pyrexia, cough, nasal ulcerations, Candida albicans infection, impaired wound healing and nasal septal perforation
- Cataracts and glaucoma
- Immunosuppression
- Hypersensitivity reactions
- Hypothalamic-pituitary-adrenal (HPA) axis effects, including growth reduction

Pediatric population

The safety in children under 6 years has not been well established. Frequency, type and severity of adverse reactions observed in the paediatric population are similar to those in the adult population.

Epistaxis

*In paediatric clinical studies of up to 12 weeks duration the incidence of epistaxis was similar between patients receiving fluticasone furoate and patients receiving placebo.

Growth retardation

***In a one-year clinical study assessing growth in pre-pubescent children receiving 110 micrograms of fluticasone furoate once daily, an average treatment difference of -0.27 cm per year in growth velocity was observed compared to placebo

4.9 Overdose
Chronic overdosage may result in signs/ symptoms of hypercorticism.

There are no data on the effects of acute or chronic overdosage with SOLSPRE F MIST nasal spray because of low systemic bioavailability and an absence of acute drug-related systemic effects

5. Pharmacological properties

5.1 Mechanism of action

The mechanism of action of corticosteroids like fluticasone works to inhibit inflammatory cells, such as mast cells, neutrophils, lymphocytes, and macrophages. Plus, fluticasone helps to inhibit the secretion of histamines, cytokines, and leukotrienes that are commonly released with asthma and allergic responses.

5.2 Pharmacodynamic Properties

Fluticasone furoate is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity. The precise mechanism through which fluticasone furoate affects rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation.

Fluticasone furoate has been shown in vitro to exhibit a binding affinity for the human glucocorticoid receptor that is approximately 29.9 times that of dexamethasone and 1.7 times that of fluticasone propionate.

5.3 Pharmacokinetic properties

Absorption

Following intranasal administration of fluticasone furoate, most of the dose is eventually swallowed and undergoes incomplete absorption and extensive first-pass metabolism in the liver and gut, resulting in negligible systemic exposure. The average absolute bioavailability is 0.50%. Oral bioavailability is on average 1.26%, and the majority of the circulating radioactivity is due to inactive metabolites.

Distribution

Binding of fluticasone furoate to human plasma proteins is greater than 99%.

Metabolism

Fluticasone furoate is cleared from systemic circulation principally by hepatic metabolism via CYP3A4. The principal route of metabolism is hydrolysis of the Sfluoromethyl carbothioate function to form the inactive 17β-carboxylic acid metabolite.

Elimination

Fluticasone furoate and its metabolites are eliminated primarily in the feces, accounting for approximately 101% and 90% of the orally and intravenously administered dose, respectively. Urinary excretion accounted for approximately 1% and 2% of the orally and intravenously administered dose, respectively

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology
Findings in general toxicology studies were similar to those observed with other glucocorticoids and are associated with exaggerated pharmacological activity. These findings are not likely to be relevant for humans given recommended nasal doses which results in minimal systemic exposure. No genotoxic effects of fluticasone furoate have been observed in conventional genotoxicity tests. Further, there were no treatment-related increases in the incidence of tumours in two year inhalation studies in rats and mice.

7. Description
Solspre F Mist is supplied for nasal use, as Nasal Spray of Fluticasone Furoate. Each Spray delivers Fluticasone Furoate 27.5 mcg.
Composition: Fluticasone Furoate 0.055% w/w and Benzalkonium Chloride 0.015% w/w (as preservative).

8. Pharmaceutical particulars
8.1 Incompatibilities
Not known.

8.2 Shelf Life
Refer Pack

8.3 Packaging Information
Refer Pack

8.4 Storage condition & handling instructions
Refer Pack

9. Patient Counseling Information
This has been prescribed for you only. Never pass it on to others. It may harm them, even if their signs of illness seem the same as yours. - If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet
It works to decrease inflammation caused by allergy (rhinitis) and is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

Children and adolescents Do not use in children under 6 years old.

Do not use it, if you are allergic to fluticasone furoate or any of the other ingredients of this medicine

It may when taken for a long time cause children to grow more slowly.
The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.

It may cause eye conditions such as glaucoma (increase in pressure in the eye) or cataracts (clouding of the lens of the eye). Tell your doctor if you had these conditions in the past, or if you notice blurred vision or other visual disturbances while you are taking it

Other medicines:
It is especially important to tell your doctor if you are taking, or have recently taken any of the following medicines:
• steroid tablets or injected steroids
• steroid creams
• medicines for asthma
• ritonavir or cobicistat, used to treat HIV
• ketoconazole, used to treat fungal infections

It should not be used at the same time with other nasal sprays containing steroids.
It is unlikely to affect your ability to drive and use machines
Do not use it if you are pregnant and breastfeeding

It contains benzalkonium chloride. Benzalkonium chloride may cause irritation or swelling inside of the nose, especially if used for a long time. Tell your doctor if you feel discomfort when using the spray
Always use this medicine exactly as your doctor has told you.
Don't exceed the recommended dose. Check with your doctor

Allergic reactions: get a doctor's help straight away

Symptoms include: -
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

In many cases, these symptoms will be signs of less serious side effects. But you must be aware that they are potentially serious — so, if you notice any of these symptoms:
Contact a doctor as soon as possible.

Very common side effects (may affect more than 1 in 10 people)
• Nosebleeds (generally minor), particularly if you use it for more than 6 weeks continuously.

Common side effects (may affect up to 1 in 10 people)
• Nasal ulceration – which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
• Headache.
• Shortness of breath

Uncommon side effects (may affect up to 1 in 100 people)

• Pain, burning, irritation, soreness or dryness in the inside of the nose. Very rare side effects (may affect up to 1 in 10,000 people)
• Small holes (perforations) in the ridge inside the nose that separates the nostrils. Not known (frequency cannot be estimated from the available data)
• Slowing of growth in children.
• Blurred vision or temporary changes to vision with long term use.
• Chest tightness causing difficulty in breathing.
Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children this side effect can cause them to grow more slowly than others. Reporting of side effects If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

10. Details of manufacturer
Refer Pack for manufacturer details.

Marketed by:
Abbott India Limited
Angel Space Lifestyle, Bldg. D-4, Gala No. 4 to 10 &
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12. Date of revision
Version 2.0, dated 23-Jan-26

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**