For the use of a registered medical practitioner or a hospital or a laboratory only
Abridged prescribing information

Generic Name
Fluticasone Furoate Nasal spray

BRAND NAME
FURAMIST Nasal spray

QUALITATIVE AND QUANTITATIVE COMPOSITION
FURAMIST Nasal spray
Each spray delivers:
Fluticasone Furoate…… 27.5 mcg

Therapeutic Indications

FURAMIST nasal spray is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in patients 2 years of age and older.

Posology and Method of Administration

FURAMIST nasal spray should be administered by the intranasal route only.

Adults and Adolescents (12 Years of Age and Over)

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.

Paediatric Patients (2 to 11 Years of Age)

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, the dosage may be decreased to 55 mcg once daily.

Contraindications
FURAMIST Nasal spray is contraindicated in patients with known hypersensitivity to fluticasone furoate or any of the excipients in this preparation.

Special Warnings and Precautions for Use

Systemic Corticosteroid Effects

- Systemic effects of nasal corticosteroid may occur, particularly at high doses prescribed for prolonged periods. Potential systemic effects may include Cushing's

syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and, more rarely, a range of psychological or behavioural effects, including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). As with all intranasal corticosteroids, the total systemic burden of corticosteroids should be considered whenever other forms of corticosteroid treatment are prescribed concurrently.

- If there is any reason to believe that adrenal function is impaired, care must be taken when transferring patients from systemic steroid treatment to fluticasone furoate nasal spray.

Visual Disturbance

- Visual disturbance may be reported with systemic and topical corticosteroid use.

Growth Retardation

- Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses. A reduction in growth velocity has been observed in children treated with fluticasone furoate. Therefore, children should be maintained on the lowest possible efficacious dose that delivers adequate symptom control.

Patients on Ritonavir

- Concomitant administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate.

Interaction with CYP3A Inhibitors

- Based on data with another glucocorticoid (fluticasone propionate) that is metabolised by CYP3A4, co-administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate.
- Caution is recommended when co-administering fluticasone furoate with potent CYP3A inhibitors, including cobicistat-containing products, as an increase in the risk of systemic side effects is expected.
- The enzyme induction and inhibition data suggest that there is no theoretical basis for anticipating metabolic interactions between fluticasone furoate and the CYP450-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.

Use in Special Populations

Pregnant Women

There are no adequate data from the use of fluticasone furoate in pregnant women. Fluticasone furoate should be used in pregnancy only if the benefits to the mother outweigh the potential risks to the foetus or child.

Nursing Mothers

It is unknown whether intranasally administered fluticasone furoate is excreted in human breast milk.

Pediatric Use

The safety and effectiveness of fluticasone furoate nasal spray in children younger than 2 years have not been established.

Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

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

Extensive first-pass metabolism by the hepatic cytochrome P450 isozyme, CYP3A4, the pharmacokinetics of fluticasone furoate may be altered in patients with hepatic impairment. The use fluticasone furoate nasal spray with caution in patients with severe hepatic impairment.

Common Side Effects

The most commonly reported adverse reactions during treatment with fluticasone furoate are epistaxis, nasal ulceration and headache. The most serious undesirable effects are rare reports of hypersensitivity reactions, including anaphylaxis (less than 1 case per 1,000 patients).

Full prescribing information available on www.ciplamed.com