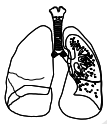

Flonaspray®

Fluticasone Propionate

Intranasal corticosteroid

COMPOSITION

Flonaspray : Each actuation delivered through a atomizing nasal applicator contains 50 µgm of Fluticasone Propionate BP.

PHARMACOLOGY

Following topical administration into the nasal mucosa, Fluticasone Propionate produces anti-inflammatory and vasoconstrictor effects. The exact mechanism of these actions remain unknown, but may involve reduction in the following: number of mediator cells (basophil, leukocytes and mast cells) at the epithelial level, number of eosinophils, sensitivity of sensory nerves to mechanical stimuli, secretory response to cholinergic receptor stimulation, and fibroblast activity. Other mechanisms may involve - inhibition of capillary dilation and permeability, stabilization of lysozomal membranes and subsequent prevention of release of proteolytic enzymes.

INDICATION

Prophylaxis and treatment of seasonal & perennial allergic rhinitis.
Prevention of recurrence of nasal polyps following surgical removal.

DOSAGE AND ADMINISTRATION

Adults

Recommended usual dosage: 02 (two) sprays (50 µgm/spray) in each nostril once daily, preferably in the morning.

In some cases, 02 (two) sprays in each nostril twice daily may be required.

Total daily doses of 200 µgm (04 sprays) should not generally be exceeded.

Children (4 to 11 years of age)
Usual dose: 01 (one) spray in each nostril once daily. In some cases, 01 (one) spray in each nostril twice daily may be required.
Total daily doses of 100 µgm (02 sprays) should not generally be exceeded.

CONTRAINDICATION AND PRECAUTION

Contraindicated in patients with a history of hypersensitivity to any of its components.

Infection of the nasal airways should be appropriately treated but do not constitute a specific contraindication to treatment with steroids.

Care must be taken while transferring patients from systemic steroid to

Flonaspray®

Fluticasone nasal spray if there is any reason to suppose that their adrenal function is impaired.

Although Fluticasone nasal spray will control seasonal and perennial allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate, appropriate additional therapy particularly to control eye symptoms.

SIDE EFFECT

The most common side effects reported are nasal irritation & stinging.

Rare instances of nasal septum perforation have been reported following intranasal administration.

As with other nasal sprays, dryness of nose and throat, unpleasant taste & smell and epistaxis have been reported rarely.

DRUG INTERACTION

None is yet known.

USE IN PREGNANCY AND LACTATION

There are no adequate & well controlled studies in pregnant women. Fluticasone propionate should be used during pregnancy, if the potential benefit justifies the potential risks to fetus.

It is not known whether Fluticasone is excreted in breast milk. As other corticosteroids are excreted in human milk, caution should be exercised when Fluticasone nasal spray is administered to a lactating mother.

STORAGE CONDITION

Store at a temperature not exceeding 30˚C. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Flonaspray® : Amber bottle containing Fluticasone Propionate aqueous suspension adequate for 120 metered doses.