

# Fluvent®

Fluticasone Propionate

## Description

**Fluvent®** nasal spray is an aqueous suspension of micronised Fluticasone Propionate for topical administration to nasal mucosa by means of a metering atomizing spray pump. Fluticasone Propionate is a synthetic corticosteroid which is a glucocorticoid receptor agonist with mainly potent anti-inflammatory activity.

## Indication

**Fluvent®** nasal spray is indicated for the prophylaxis & treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis in adult and paediatric patients 4 years of age and older. It has potent anti-inflammatory activity on the nasal mucosa without detectable systemic activity. It is also indicated to prevent the reoccurrence of nasal polyps following surgical removal.

## Dosage & administration

**Adults & children over 12 years of age:** The starting dose is two sprays (100 micrograms) in each nostril once daily, preferably in the morning, increased to maximum twice daily if required. Once symptoms are under control, reduce to one spray (50 micrograms) into each nostril once daily.

**Children 4 to 11 years of age:** One spray (50 micrograms) into each nostril once daily preferably in the morning, increased to maximum twice daily if required. The maximum daily dose should not exceed two sprays in each nostril.

## Use in pregnancy & lactation

Pregnancy category C. 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 Propionate is excreted in breast milk. As other corticosteroids are excreted in human milk, caution should be exercised when Fluticasone Propionate nasal spray is administered to a lactating mother.

## Side effects

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.

## Precautions

Intranasal corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Rarely, immediate hypersensitivity reactions or contact dermatitis may occur after the administration of Fluticasone Propionate nasal spray. Rare instances of wheezing, nasal septum perforation, cataracts, glaucoma, and increased intraocular pressure have been reported following the intranasal application of corticosteroids, including Fluticasone propionate. Although systemic effects have been minimal with recommended doses of Fluticasone Propionate nasal spray, potential risk increases with larger doses. Therefore, larger than recommended doses of Fluticasone Propionate should be avoided.

## Contraindications

Fluticasone Propionate is contraindicated in those patients with a known history of hypersensitivity to any of the components of the preparation.

## Drug interactions

Fluticasone Propionate is a substrate of cytochrome P450 3A4. Caution should be exercised when co-administering known strong cytochrome P450 3A4 inhibitors (e.g. Ketoconazole, Ritonavir) as there is potential for increased systemic exposure to Fluticasone Propionate.

## Pharmaceutical precautions

Store in a cool & dry place protected from light. Keep away from the reach of children.

## Presentation

**Fluvent®** nasal spray: Each actuation delivers Fluticasone Propionate BP 50 micrograms.

## Package quantities

**Fluvent®** nasal spray : Each container contains Fluticasone Propionate BP for 120 metered sprays.

® Registered Trade Mark



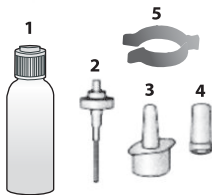
**ACI Limited**

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# How to use nasal spray

## Parts of device

1. Plastic container
2. Metered valve
3. Nasal applicator
4. Dust cap
5. Clip



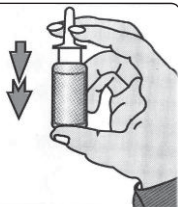
## Preparing the container

- Remove the dust cover by pulling upwards.
- Pull off the white plastic clip.
- Gently shake the container before use.



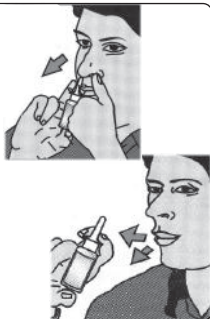
## If you are using the spray for the first time

- Hold the container in upright position.
- Press the nasal applicator 3-4 times until a fine mist comes out from the container. This is called priming.
- The nasal spray is now ready to use.



## Using the spray

- Before using your nasal spray, gently blow your nose to clear your nostrils.
- Close one nostril with your finger. Hold the container upright and put the nozzle deep into the other nostril as far as it is comfortable.
- Gently breathe through your nose with your mouth closed.
- While breathing in, press down the nasal applicator to deliver one spray.
- Then breathe out through your mouth.



## After using the spray

- To keep the spray nozzle clean, wipe it carefully with a clean tissue or handkerchief after using it.
- Press the plastic clip back into place to avoid accidental release of the spray.
- Put the dust cover on the nozzle.

## If the nasal spray is not being used for more than 2 weeks

- Prime (3-4 sprays) it again before use.
- Always shake the container gently before use.

## Cleaning process

The nasal applicator should be cleaned at least once a week or when it becomes blocked.

- Remove the dust cap.
- Push the nasal applicator upward to detach the nasal applicator from the valve.
- Wash the applicator and dust cap with warm water.
- Shake the excess water and leave it to dry in a normal place. Avoid applying additional heat.
- Push the applicator back on top of the bottle and re-fix the dust cap.
- Reprime the nasal spray until a fine mist is formed and use normally.