

FLUTINIDE NASAL SPRAY

Fluticasone propionate 0.05%w/v (50mcg/dose)

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This leaflet answers some common questions about FLUTINIDE Nasal Spray. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking FLUTINIDE Nasal Spray against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What FLUTINIDE Nasal Spray is used for

It is used to prevent and to treat allergic rhinitis (an inflammation of the nasal passages caused by allergic reaction) in adults and children aged 4 years and over.

Your doctor may have suggested this medication for conditions other than those listed in this leaflet. If you have not discussed this with your doctor or are not sure why you are being given this medication, speak to your doctor. Do not stop using this medication without consulting your doctor.

How FLUTINIDE Nasal Spray works

FLUTINIDE Nasal Spray belongs to a group of medicines called corticosteroid (steroid for short) which has an anti-inflammatory action. The tiny amounts sprayed into your nose help to reduce swelling and irritation.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use FLUTINIDE Nasal Spray

-When you must not use it

Do not use this medicine if:

- you have an allergy or have had an adverse reaction to any of this medicine related ingredients.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine:

- after the expiry date printed on the pack, or
- if the packaging is torn or shows signs of tampering.

-Before you start to use it

Tell your doctor or pharmacist:

- Your medical conditions or allergies you may have, and any significant facts about your health
- If you have infection of the nasal (nose) airways.

Growth retardation has been reported in children receiving nasal corticosteroid. It is recommended to regularly monitor the height of children receiving prolonged treatment of this medication.

Pregnancy and breast feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, plan to become pregnant or breastfeeding.
- Safe use during pregnancy and breastfeeding has not been established.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your pharmacist or doctor if:

- you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir)
- you are taking certain medicines used to treat fungal infections (e.g. ketoconazole and itraconazole)

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use FLUTINIDE Nasal Spray

-How much to use

Adults and children over 12 years of age: 2 sprays into each nostril once a day, preferably in the morning.

In some cases two sprays into each nostril twice daily may be required. Once symptoms are under control, a maintenance dose of one spray per nostril once a day may be used. The maximum daily dose should not exceed four sprays into each nostril.

Elderly patients: Same as the normal adult dosage.

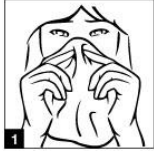
Adolescents and children (4 years of age and older): A dose of 1 spray into each nostril once (or twice) daily preferably in the morning. The

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maximum daily dose should not exceed two sprays into each nostril. Please refer to your doctor or pharmacist.

How to use the spray:



1. Blow the nose gently to clear nostrils.



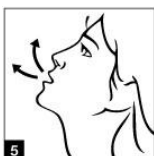
2. Shake the bottle gently.



3. For first time use, hold the bottle upright and fill the pump by pressing the nozzle downwards and releasing it 5 times, until a fine spray is produced

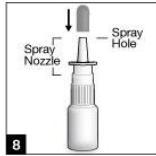


4. Close one nostril with one finger. Hold the bottle upright and insert the nozzle into the nostril as far as is comfortable. Whilst breathing in gently through the nose with the mouth closed, press the bottle upwards once to deliver one spray.



5. Breathe out through the mouth.

6. Repeat steps 4 and 5 for the other nostril.
7. For patients aged 12 years and older, steps 4, 5 and 6 should be repeated once more to achieve recommended dosage of 2 sprays into each nostril.



8. To keep the spray nozzle clean, wipe it carefully with a clean tissue after each use and replace the cap.

If the nasal spray has not been used for 2 weeks or more, spray once into the air before use. Point the nozzle away while doing this.

Always shake the bottle gently before use. If the spray does not work and it may be blocked, clean it as follows. NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

The nasal spray should be cleaned at least once a week or more often if it gets blocked.

How to clean the spray:

1. Remove the cap and pull off the spray nozzle only.
2. Soak the dust-cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.
3. Shake or tap off the excess water and allow to air-dry.
4. Re-fit the spray nozzle.
5. Prime the unit as necessary until a fine mist is produced and use as normal.

-When to use it

It is preferably to administer the sprays in the morning.

-How long to use it

Follow carefully all directions given to you by your doctor and the pharmacist.

If you are not sure how long you should be using FLUTINIDE Nasal Spray, check with your doctor. If your condition does not improve after the treatment course, or if it becomes worse, contact your doctor.

-If you forget to use it

It is important to use this medication exactly as prescribed by your doctor. If you forget to apply this medication, apply it as soon as you remember. If it is almost time for your next application, skip the missed dose and continue with your regular schedule. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

There is no available data on the effects of overdosage with FLUTINIDE Nasal Spray. Long term usage of corticosteroid may cause suppression of HPA axis function (resulting in inadequate cortisol 'stress hormone' production).

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

While you are using FLUTINIDE Nasal Spray

-Things you must do

Take your medicine exactly as your doctor has told you. Tell your doctor immediately if you become pregnant while taking this medication.

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking FLUTINIDE Nasal Spray

-Things you must not do

Do not continue FLUTINIDE Nasal Spray if you have irritation or sensitization after using this medicine.

Do not exceed maximum daily dose. Ask your doctor or pharmacist.

Do not give this medication to anyone else, even if they have the same symptoms as you do. It can be harmful for people to use this

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medication if their doctor has not prescribed it.

-Things to be careful of

This medication should not be used in or near eye area. If this occurs, bathe your eye with eyewash if possible. Your eye may sting. If you start having any problem with your sight or your eye is sore, contact your doctor immediately.

Do not swallow this medication.

Small quantity may not cause any harm. If you accidentally swallow in a larger quantity, please contact your doctor immediately.

Side effects

Like other medicines, FLUTINIDE Nasal Spray can cause some side effects.

Stop applying FLUTINIDE Nasal Spray and immediately contact your doctor if you notice any of the following symptoms. You may be having an allergic reaction.

- severe and sudden onset of itching, redness, hives or a rash around the application area
- nausea or vomiting
- swelling of the face, lips, mouth, tongue or throat with breathing difficulties.

Other possible side effects which are common can also occur. You should tell your doctor about these as soon as possible.

- Irritation or dryness of the site of treatment especially the nose and throat
- Headache
- Unpleasant taste or smell

Hypersensitivity (allergy) to Fluticasone propionate or the ingredients of the nasal spray.

Very common side effects would be nose-bleeding.

Other possible side effects can also occur. You should tell your doctor about these as soon as possible.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of FLUTINIDE Nasal Spray

-Storage

Store below 30°C. Keep in a cool dry place. Keep out of reach of children. Keep bottle in upright position.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

FLUTINIDE Nasal Spray is an opaque off-white slight viscous suspension

Available in 15ml plastic metered spray bottle.

-Ingredients

Active ingredient:
Fluticasone propionate 0.05% w/v (50mcg/dose)

Inactive ingredients:
Benzalkonium Chloride,
Polysorbate 80, Microcrystalline Cellulose, Carboxymethylcellulose Sodium, Dextrose, Hydrochloric Acid, Disodium Edetate and Purified Water

-MAL number

MAL11105001AZ

Manufacturer and Product Registration Holder

Manufacturer

HOE Pharmaceuticals Sdn. Bhd.
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Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
MALAYSIA.

Product Registration Holder

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