

DISCLAIMER

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Patient Information

Fluticasone Propionate Nasal Spray, 50 mcg (floo-TIK-a-son)

Read the Patient Information that comes with fluticasone propionate nasal spray before you start using it and each time you get a refill. There may be new information. This Patient Information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is fluticasone propionate nasal spray?

Fluticasone propionate nasal spray is a prescription medicine used to treat non-allergy nasal symptoms such as runny nose, stuffy nose, sneezing, and nasal itching in adults and children aged 4 years and older.

It is not known if fluticasone propionate nasal spray is safe and effective in children younger than 4 years of age.

Who should not use fluticasone propionate nasal spray?

Do not use fluticasone propionate nasal spray if you are allergic to fluticasone propionate or any of the ingredients in fluticasone propionate nasal spray. See “What are the ingredients in fluticasone propionate nasal spray?” below for a complete list of ingredients.

What should I tell my healthcare provider before using fluticasone propionate nasal spray?

Tell your healthcare provider about all of your health conditions, including if you:

- have or have had nasal sores, nasal surgery, or nasal injury.
- have eye problems, such as cataracts or glaucoma.
- have an immune system problem.
- are allergic to any of the ingredients in fluticasone propionate nasal spray, any other medicines, or food products. See “What are the ingredients in fluticasone propionate nasal spray?” below for a complete list of ingredients.
- have any type of viral, bacterial, or fungal infection.
- are exposed to chickenpox or measles.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if fluticasone propionate nasal spray may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if fluticasone propionate nasal spray passes into your breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Fluticasone propionate nasal spray and certain other medicines may interact with each other. This may cause serious side effects. Especially, tell your healthcare provider if you take antifungal or anti-HIV medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use fluticasone propionate nasal spray?

Read the step-by-step instructions for using fluticasone propionate nasal spray at the end of this Patient Information.

- Fluticasone propionate nasal spray is for use in your nose only. Do not spray it in your eyes or mouth.
- Children should use fluticasone propionate nasal spray with an adult’s help, as instructed by the child’s healthcare provider.
- Use fluticasone propionate nasal spray exactly as your healthcare provider tells you. Do not use fluticasone propionate nasal spray more often than prescribed.
- Fluticasone propionate nasal spray may take several days of regular use for your rhinitis symptoms to get better. If your symptoms do not improve or get worse, call your healthcare provider.
- You will get the best results if you keep using fluticasone propionate nasal spray regularly each day without missing a dose. After you begin to feel better, your healthcare provider may decrease your dose. **Do not** stop using fluticasone propionate nasal spray unless your healthcare provider tells you to do so.

What are the possible side effects of fluticasone propionate nasal spray?

Fluticasone propionate nasal spray may cause serious side effects, including:

- **nose problems.** Nose problems may include:
 - **nose bleeds.**
 - **sores (ulcers) in your nose.**
 - **a certain fungal infection in your nose, mouth, and/or throat (thrush).**
 - **hole in the cartilage of your nose (nasal septal perforation).** Symptoms of nasal septal perforation may include:
 - crusting in the nose
 - nose bleeds
 - runny nose
 - whistling sound when you breathe
 - **slow wound healing.** You should not use fluticasone propionate nasal spray until your nose has healed if you have a sore in your nose, have had surgery on your nose, or if your nose has been injured.
- **eye problems including glaucoma and cataracts.** You should have regular eye exams while you use fluticasone propionate nasal spray.
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following signs of a serious allergic reaction:
 - rash
 - hives
 - swelling of your face, mouth, and tongue
 - breathing problems

- **weakened immune system and increased chance of getting infections (immunosuppression).** Taking medicines that weaken your immune system makes you more likely to get infections and can make certain infections worse. These infections may include tuberculosis (TB), ocular herpes simplex infections, and infections caused by fungi, bacteria, viruses, and parasites. Avoid contact with people who have a contagious disease such as chickenpox or measles while using fluticasone propionate nasal spray. If you come in contact with someone who has chickenpox or measles call your healthcare provider right away. Symptoms of an infection may include:

- fever
- pain
- aches
- chills
- feeling tired
- nausea
- vomiting

- **lowered steroid hormone levels (adrenal insufficiency).** Adrenal insufficiency happens when your adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking medicine containing an inhaled steroid (such as fluticasone propionate nasal spray). Symptoms of adrenal insufficiency may include:

- feeling tired
- lack of energy
- weakness
- nausea and vomiting
- low blood pressure

- **slowed growth in children.** A child’s growth should be checked often.

The most common side effects of fluticasone propionate nasal spray include:

- headache
- sore throat
- nose bleeds
- nose burning or itching
- nausea and vomiting
- trouble breathing
- cough

Tell your healthcare provider about any side effect that bothers you or does not go away.

These are not all the side effects with fluticasone propionate nasal spray. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088.

How do I store fluticasone propionate nasal spray?

- Store fluticasone propionate nasal spray between 39°F and 86°F (4°C and 30°C).

Keep fluticasone propionate nasal spray and all medicines out of the reach of children.

General information about the safe and effective use of fluticasone propionate nasal spray.

Medicines are sometimes prescribed for purposes not mentioned in a Patient Information leaflet. Do not use fluticasone propionate nasal spray for a condition for which it was not prescribed. Do not give your fluticasone propionate nasal spray to other people, even if they have the same condition that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about fluticasone propionate nasal spray. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about fluticasone propionate nasal spray that was written for healthcare professionals.

What are the ingredients in fluticasone propionate nasal spray?

Active ingredient: fluticasone propionate.

Inactive ingredients: benzalkonium chloride (0.02% w/w), carboxymethylcellulose sodium, dextrose, microcrystalline cellulose, phenylethyl alcohol (0.25% w/w), polysorbate 80, and purified water.

Manufactured by:
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701
Made in USA

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