

## PATIENT INFORMATION

### **XHANCE® (ex hans) (fluticasone propionate) nasal spray, 93 mcg**

#### **What is XHANCE?**

XHANCE is a prescription medicine used to treat chronic rhinosinusitis with nasal polyps in adults. It is not known if XHANCE is safe and effective in children.

**Do not use XHANCE** if you are allergic to fluticasone propionate or any of the ingredients in XHANCE. See the end of this Patient Information leaflet for a complete list of ingredients in XHANCE.

#### **Before using XHANCE, tell your healthcare provider about all of your medical 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.
- have any type of viral, bacterial, or fungal infection.
- are exposed to chickenpox or measles.
- have weak bones (osteoporosis).
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if XHANCE may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XHANCE 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.

XHANCE 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 XHANCE?**

Read the **Instructions for Use** leaflet for information about the right way to use XHANCE.

- Use XHANCE exactly as your healthcare provider tells you.
- **Do not** use XHANCE more often than prescribed. Ask your healthcare provider if you have any questions.
- XHANCE is for use in your nose only. **Do not spray it in your eyes or mouth.**
- XHANCE may take several days of regular use for your symptoms to get better. It may take several months for the medicine to have its greatest effect. If your symptoms do not improve or get worse, call your healthcare provider.
- You will get the best results if you keep using XHANCE regularly twice each day without missing a dose. Do not stop using XHANCE unless your healthcare provider tells you to do so.
- If you miss a dose of XHANCE, take it as soon as you remember the same day. **Do not** take more than your prescribed dose of XHANCE each day.

#### **What are the possible side effects of XHANCE?**

**XHANCE may cause serious side effects, including:**

- **Nasal problems.** Symptoms of nasal problems may include:
  - nose bleeds.
  - crusting in the nose.
  - sores (ulcers) in the nose.
  - hole in the cartilage of the nose (nasal septal perforation). A whistling sound when you breathe may be a symptom of nasal septum perforation.
  - thrush (candida), a fungal infection in your nose and throat. Tell your healthcare provider if you have any redness or white colored patches in your nose or mouth.
  - slow wound healing. You should not use XHANCE 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 XHANCE. Call your healthcare provider if you have vision changes while using XHANCE.
- **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
  - low blood pressure
- **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), herpes simplex infections of the eyes (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 XHANCE. 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

- **Reduced adrenal function (adrenal insufficiency).** Reduced adrenal function 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 a steroid inhaled into the lungs or for use in the nose. Symptoms of reduced adrenal function may include:

- tiredness
- weakness
- nausea and vomiting
- low blood pressure

- **Weak bones (osteoporosis).**

- **Slowed growth in children.** A child's growth should be checked often.

**The most common side effects of XHANCE include:**

- nose bleeds
- sores (ulcers) in your nose
- pain or swelling of your nose or throat (nasopharyngitis)
- redness in your nose
- nasal congestion
- sinus infection
- headache

These are not all the possible side effects of XHANCE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store XHANCE?**

- Store XHANCE at room temperature between 59°F and 77°F (15°C and 25°C).
- Protect XHANCE from extreme heat, cold and light.
- Throw away XHANCE after using 120 sprays after initial priming. Even though the bottle may not be completely empty, you may not get the correct dose of medicine if you continue to use it.
- The XHANCE Bottle is made of glass. Do not remove the base from the bottle.

**Keep XHANCE and all medicines out of the reach of children.**

#### **General information about the safe and effective use of XHANCE.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XHANCE for a condition for which it was not prescribed. Do not give your XHANCE to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about XHANCE that is written for health professionals.

#### **What are the ingredients in XHANCE?**

**Active ingredient:** fluticasone propionate

**Inactive ingredients:** microcrystalline cellulose, carboxymethylcellulose sodium, dextrose, benzalkonium chloride, polysorbate 80, edetate disodium dihydrate, sodium hydroxide and hydrochloric acid (to adjust pH), and purified water

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