XHANCE®
(fluticasone propionate) nasal spray 93 mcg

EXPERIENCE
THE DIFFERENCE

INDICATION
XHANCE is a prescription medicine used to treat nasal polyps in adults.

IMPORTANT SAFETY INFORMATION
Do not use XHANCE if you are allergic to fluticasone propionate or any of the ingredients in XHANCE.

Please see additional Important Safety Information, and enclosed Instructions for Use and Patient Information.
EXPERIENCE THE DIFFERENCE

XHANCE USES YOUR BREATH TO HELP REACH THE SOURCE OF THE PROBLEM

XHANCE is the only FDA-approved prescription nasal spray that uses an Exhalation Delivery System to treat nasal polyps.

You blow into XHANCE, you don’t sniff. Your breath helps deliver medicine high and deep into your nasal passages, where nasal polyps occur. That means the medicine should reach the source of the problem.

Because you blow using your mouth when you use XHANCE, you may also limit the medicine from dripping down your throat, so more medicine is directed to where it’s needed to help treat your symptoms.

SYMPTOM RELIEF WITHIN REACH

XHANCE is approved for the treatment of nasal polyps in adults. In clinical trials,* XHANCE improved symptoms of nasal polyps, such as nasal congestion, as early as 2 weeks, and symptoms continued to get better over time. In addition, XHANCE significantly reduced the size of nasal polyps over time.

*In 16-week clinical trials.

IMPORTANT SAFETY INFORMATION (continued)
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. It is very important to tell your healthcare provider if you take antifungal or anti-HIV medicines.
NASAL POLYPS AND THEIR SYMPTOMS

Nasal polyps result from chronic inflammation and occur high and deep within your nasal passages and sinuses. This makes them difficult to see with a routine nasal exam. In fact, you may not even know you have nasal polyps.

The symptoms of nasal polyps last at least 3 months. Because nasal polyps and associated inflammation block passages high and deep in the nose, nasal sprays may have a hard time reaching them. That may be why you’re not getting the relief you need.

SIGNS AND SYMPTOMS OF NASAL POLYPS:

- **NASAL CONGESTION**
- **RUNNY NOSE/POST-NASAL DRIP**
- **FACIAL PAIN OR PRESSURE**  
  (USUALLY IN THE NOSE AND SINUS REGION)
- **REDUCED SENSE OF SMELL**

FOR BEST RESULTS

- Use XHANCE consistently; do not discontinue use unless instructed by your doctor
- XHANCE should be used twice daily
- Remember to refill your prescription monthly

Please see additional Important Safety Information, and enclosed Instructions for Use and Patient Information.
Watch the step-by-step video at XHANCE.com/#how-to-use

GET STARTED
For full instructions on using XHANCE, please see enclosed FDA-approved Instructions for Use.

COMPONENTS
- Nosepiece
- Cap
- Flexible mouthpiece
- Indented grip
- Bottle

GRIP
- One-handed grip OR Two-handed grip

PRIMING
Before first use
A new XHANCE must be primed. Follow these simple steps.

- Remove the cap and shake
- Pump 7 times, or until you see a fine mist

You’re now ready to use XHANCE!

Note: If you have not used XHANCE for 7 or more days, re-prime by spraying 2 times.

Please see additional Important Safety Information, and enclosed Instructions for Use and Patient Information.
**USING XHANCE**

1. **SEAL**
   - First, shake. Then place your fingers on the indented grip BELOW the mouthpiece.
   - Gently insert the nosepiece into your nose and flexible mouthpiece into your mouth.
   - **Keep a tight seal between the nosepiece and your nostril**

2. **AIM**
   - Aim the device upward between your eyes.
   - **It may help to use a mirror**

3. **BLOW**
   - Take a deep breath and blow hard into the mouthpiece. Imagine you are blowing up a balloon.
   - **Blow, don't sniff...and don't block other nostril!**
   - **DON'T STOP BLOWING**

4. **PRESS**
   - Keep blowing as you press the bottle with your thumb, releasing the medicine deep into your nasal passages.
   - **Keep blowing hard while pressing the bottle**

**Now repeat these steps for your other nostril**

**REMEMBER to use XHANCE twice daily**
IMPORTANT SAFETY INFORMATION (continued)

XHANCE can cause nasal problems such as nosebleeds, crusting in the nose, sores (ulcers) in the nose, hole in the cartilage of the nose (nasal septal perforation).

XHANCE can cause eye problems including glaucoma and cataracts. You should have regular eye exams when using XHANCE.

Call your healthcare provider right away or get emergency medical care if you get any of these signs of a serious allergic reaction: rash, hives, swelling of your face, mouth, and tongue, breathing problems, and low blood pressure.

XHANCE can weaken your immune system, make you more likely to get infections, and can make certain infections worse. 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.

XHANCE can cause reduced production of steroid hormones by your adrenal gland, resulting in tiredness, weakness, nausea and vomiting, and low blood pressure.

XHANCE can weaken bones (osteoporosis).

The most common side effects of XHANCE include nosebleeds, thrush (fungal infection in the nose and throat), sores (ulcers) in the nose, pain or swelling of the nose or throat (nasopharyngitis), redness of the nose, nasal congestion, sinus infection, slow wound healing and headache.

Before using XHANCE, carefully read the FDA-approved Patient Information and Instructions for Use.

INDICATION

XHANCE is a prescription medicine used to treat nasal polyps in adults.

Please see enclosed Instructions for Use and Patient Information.

WATCH THE STEP-BY-STEP VIDEO

AT XHANCE.COM/#HOW-TO-USE
## PATIENT INFORMATION

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

### What is XHANCE?

XHANCE is a prescription medicine used to treat 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 the medicine in 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.
  - crust 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.
- **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

• **Reduced adrenal function (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 a steroid inhaled into the lungs or for use in the nose. Symptoms of adrenal insufficiency 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 side effects associated with 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 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.

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, and purified water

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Patented. See www.xhance.com/patents
For more information, go to www.XHANCE.com or call 1-833-678-6673.
### Important information about XHANCE

- XHANCE is for use in your nose only. Do not spray in your eyes or mouth.
- XHANCE delivers your dose of medicine into your nose when you press the Bottle while blowing into the Flexible Mouthpiece (See Figure B).
- Do not share XHANCE with other people.
- Shake XHANCE before each use.
- Do not block second nostril while blowing.
- Do not place fingers above or over the Flexible Mouthpiece.
- The XHANCE Bottle is made of glass and can be damaged if dropped or hit too hard. If you drop or hit XHANCE, call 1.833.678.6673.

### Prime XHANCE before first use

**Priming XHANCE:**

**Step 1:** Remove the Cap (See Figure C).

**Step 2:** Shake XHANCE.

**Step 3:** Press the Bottle 7 times or until you see a fine mist (See Figure D).

Keep the Tapered Tip of XHANCE pointed away from your face while priming. When you see a fine mist of medicine, XHANCE is ready to use.

**Important:** If you have not used XHANCE for 7 or more days, re-prime by spraying 2 times away from your face.

### Steps for using XHANCE after priming

**Step 1:** Remove the Cap.

**Step 2:** Shake XHANCE (See Figure E).

**Step 3:** Hold XHANCE by placing your fingers on the Indented Grip below the Flexible Mouthpiece. You can use 1 hand (See Figure F), or 2 hands (See Figure G) to hold XHANCE.

Do not place your fingers above or over the Flexible Mouthpiece.
### Step 8: While still blowing hard into the Flexible Mouthpiece, use your thumb to press the Bottle to deliver medicine into your nostril (See Figure L).

### Step 7: Blow hard into the Flexible Mouthpiece like you are blowing up a balloon (See Figure K).

- Do not try to breathe in through your nose or sniff while blowing into the Flexible Mouthpiece.
- Do not close or block your other nostril. This could prevent the air you blow into the Flexible Mouthpiece from leaving out through the other nostril.

### Step 6: Aim the device upward. This will help the medicine go deep into your nostril (See Figure J).

- Note: You can use a mirror to help you aim the device upward.

### Step 5: Insert the Flexible Mouthpiece in your mouth, while keeping the Nosepiece in your nostril (See Figure I).

- Make sure that the Flexible Mouthpiece is secure in the mouth and the Nosepiece remains sealed in the nostril during use.

- Note: You can bend the Flexible Mouthpiece up and down to get it into your mouth while keeping the Nosepiece deep in your nostril.

### Step 4: Gently insert the Nosepiece into the nostril. While still holding XHANCE on the Indented Grip below the Flexible Mouthpiece, insert the Nosepiece as far back into 1 nostril as comfortable (See Figure H). This helps to keep a tight seal between the Nosepiece and your nostril.

- Important: Keep a tight seal between the Nosepiece and your nostril.

### Step 3: Blow hard into the Flexible Mouthpiece like you are blowing up a balloon (See Figure K).

- Do not try to breathe in through your nose or sniff while blowing into the Flexible Mouthpiece.
- Do not close or block your other nostril. This could prevent the air you blow into the Flexible Mouthpiece from leaving out through the other nostril.

### Step 2: Insert the Flexible Mouthpiece in your mouth, while keeping the Nosepiece in your nostril (See Figure I).

- Make sure that the Flexible Mouthpiece is secure in the mouth and the Nosepiece remains sealed in the nostril during use.

- Note: You can bend the Flexible Mouthpiece up and down to get it into your mouth while keeping the Nosepiece deep in your nostril.

### Step 1: Insert the Flexible Mouthpiece in your mouth, while keeping the Nosepiece in your nostril (See Figure I).

- Make sure that the Flexible Mouthpiece is secure in the mouth and the Nosepiece remains sealed in the nostril during use.

- Note: You can bend the Flexible Mouthpiece up and down to get it into your mouth while keeping the Nosepiece deep in your nostril.

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**Did I do it right?**

- ✔ Shake before each use.
- ✔ Keep a snug fit in nose and mouth.
- ✔ Continue blowing forcefully while pressing the Bottle.
- ✔ Do not sniff, inhale, or block second nostril.
- ✔ Administer only the prescribed number of sprays in each nostril.

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**Cleaning and Caring for XHANCE**

- You do not need to clean XHANCE. If you prefer to clean the device, remove the Cap and use a clean, dry, lint-free cloth to wipe after each use.
- Replace the Cap and store XHANCE in a clean, dry place.
- The XHANCE Bottle is made of glass and can be damaged if dropped or hit too hard. If you drop or hit XHANCE, call 1.833.678.6673. Do not use if damaged.

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**How should I store XHANCE?**

- Store at room temperature (between 15°C and 25°C; 59°F and 77°F).
- Protect XHANCE from 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.

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

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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