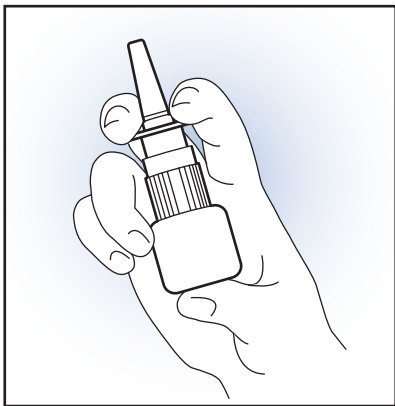
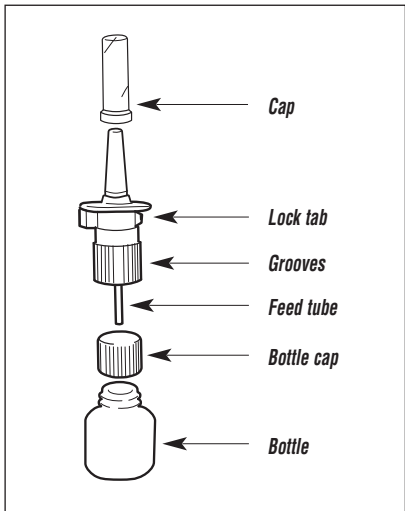


Fortical[®]
calcitonin-salmon (rDNA origin)
Nasal Spray

Patient Information
and Instructions
for Use



UPHER-SMITH



Patient Information
Fortical® [fōr-ti-kāl]
calcitonin-salmon (rDNA origin)
Nasal Spray

Read the Patient Information that comes with Fortical® Nasal Spray before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is Fortical® Nasal Spray?

Fortical® Nasal Spray is a prescription medicine used to treat osteoporosis in women, who went through menopause (postmenopausal women) at least 5 years ago.

Fortical® Nasal Spray contains calcitonin salmon, a man-made protein that is similar to a protein occurring in the human body. When you spray Fortical® Nasal Spray into your nostril, it is rapidly absorbed by the blood vessels lining your nasal passages. It then travels into your bloodstream and on to your bones where it has been shown to slow down bone loss at the spine. Slowing down bone

loss, while new bone building continues, helps to increase bone mass at the spine.

Fortical® Nasal Spray is taken with calcium and vitamin D supplements recommended by your doctor, to help slow down further bone loss. If you are not getting enough calcium and vitamin D in your daily diet, your doctor may recommend a calcium or vitamin D supplement. The amount of calcium and vitamin D needed each day can vary from person to person. Most people generally require at least 1000 mg of calcium and 400 International Units of vitamin D each day. Vitamin D is necessary for your body to use calcium to build bone material. That is why your doctor may have recommended that you add a vitamin D supplement to your diet. It is important to take all the calcium and vitamin D supplements your doctor directs each day.

Who should not use Fortical® Nasal Spray?

Do not use Fortical® Nasal Spray if you are allergic to the calcitonin salmon protein.

What should I tell my doctor before using Fortical® Nasal Spray?

Tell your doctor about all your health conditions, including if you:

- are pregnant. It is not known if Fortical® Nasal Spray can cause harm to an unborn baby if it is used during pregnancy.
- are breast-feeding. It is not known if Fortical® Nasal Spray passes into your breast milk.

Tell your doctor and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I use Fortical® Nasal Spray?

- Periodic nasal exams are recommended. Your doctor should do a nasal exam before you start using Fortical® Nasal Spray and if you have any nasal discomfort while using it.
- Use Fortical® Nasal Spray exactly as your doctor prescribes it. See the detailed Patient Instructions for Use at the end of this leaflet.

- Before using a new bottle of Fortical® Nasal Spray for the first time, take it out of the refrigerator and let the medicine warm to room temperature. Using Fortical® Nasal Spray directly from a refrigerator without being warmed to room temperature may cause you to have nasal discomfort.
- Before using a new bottle of Fortical® Nasal Spray for the first time, you will need to prime the pump at least 5 times until a full spray is produced. See the detailed Assembly Instructions and Using Fortical® Nasal Spray sections at the end of this Patient Information Leaflet for directions on how to prime a new bottle of Fortical® Nasal Spray and how to properly use Fortical® Nasal Spray.
- One spray in either nostril will give you the right daily dose of Fortical® Nasal Spray. Change (alternate) between using the right nostril one day and the left nostril the next day. Each bottle of Fortical® Nasal Spray contains enough medicine for 30 days of dosing.
- After priming the pump, do not use Fortical® Nasal Spray for more than 30 doses. Even though the container may not be completely empty, you may not get the correct

dose of medicine. Safely throw away the empty bottle of Fortical® Nasal Spray after you have used 30 doses.

- If you miss a dose, or forget to use Fortical® Nasal Spray, use it as soon as you can. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use extra medicine to make up for the missed dose.
- If you use too much Fortical® Nasal Spray, tell your doctor.

What are the possible side effects of Fortical® Nasal Spray?

Serious allergic reactions can happen with Fortical® Nasal Spray. See "Who should not use Fortical® Nasal Spray".

Get emergency medical help right away if you have any of the following symptoms of a serious allergic reaction:

- trouble breathing
- swelling of your face, throat or tongue
- rapid heartbeat
- chest pain
- feel faint or dizzy

The most common side effects of Fortical® Nasal Spray include:

- nasal symptoms including: runny nose, dryness, crusting, sores, infection, redness, irritation, itching, tenderness, nosebleed, discomfort across bridge of nose
- back and joint pain
- headache

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Fortical® Nasal Spray. For more information, ask your doctor or pharmacist.

How should I store Fortical® Nasal Spray?

- Keep new, unopened bottles of Fortical® Nasal Spray in the refrigerator, between 36°F to 46°F (2°C to 8°C).
- Do not freeze.
- Keep the bottle of Fortical® Nasal Spray away from light.
- Allow the Fortical® Nasal Spray to reach room temperature before using it and for the first time.

- Tighten the pump securely to the bottle (see Step 3 and 4 in the Patient Instructions of Use - Assembly Instructions). This will help to ensure a good seal between the pump and the bottle.
- After opening a new bottle of Fortical® Nasal Spray, store at room temperature, 68°F to 77°F (20°C to 25°C).
- Each bottle of Fortical® Nasal Spray contains enough medicine for 30 doses. Throw away the empty bottle of Fortical® Nasal Spray after you have used 30 doses.

Keep Fortical® Nasal Spray and all other medicines out of the reach of children.

What are the ingredients in Fortical® Nasal Spray?

Active Ingredient: Calcitonin-salmon

Inactive Ingredients: Sodium Chloride USP, Citric Acid USP, Phenethyl Alcohol USP, Benzyl Alcohol NF, Polysorbate 80 NF, Hydrochloric Acid NF or Sodium Hydroxide NF and Purified Water USP.

General Information about Fortical® Nasal Spray

This medication was prescribed for you by your doctor for a particular condition. Do not use Fortical® Nasal Spray to

treat a condition for which it was not prescribed. Do not give Fortical® Nasal Spray to other people, even if they have the same symptoms you have. It may harm them.

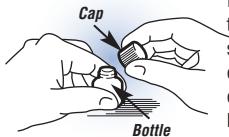
This patient information leaflet summarizes the most important information about Fortical® Nasal Spray. If you would like more information about Fortical® Nasal Spray talk with your doctor. You can ask your doctor or pharmacist for information about Fortical® Nasal Spray that is written for health professionals. For more information, go to www.upsher-smith.com or call 1-800-654-2299.

General Information about Osteoporosis

The amount of estrogen produced by a woman's body is greatly reduced after menopause. Estrogen helps to balance bone growth and keep bones strong. When estrogen is reduced, your body may remove old bone cells faster than it replaces them with new bones cells. Bones can become weak and brittle, and more likely to break (fracture). This condition is known as postmenopausal osteoporosis. Fortical® Nasal Spray may increase bone density, but there is no information to show that it decreases the risk of fracture.

Patient Instructions for Use

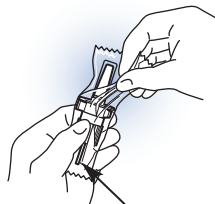
Assembly Instructions



Step 1.

Step 1. Opening the Bottle.

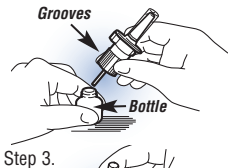
If your pharmacist attached the pump for you, skip to step 4. Otherwise, set bottle on a flat surface like table or counter top. Hold the bottle firmly while unscrewing cap to avoid spilling any Fortical® Nasal Spray.



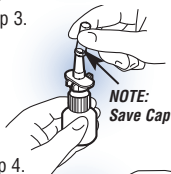
Step 2. *Feed tube*

Step 2. Unwrapping the Pump.

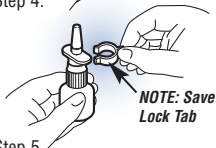
Carefully cut the wrapper with scissors or knife, and tear away from the pump. Be careful not to cut, bend, or touch the feed tube at bottom.



Step 3.



Step 4.



Step 5.

Save the lock tab, and push it back onto the pump after each use to avoid accidentally wasting any

Fortical® Nasal Spray

Step 3. Attaching the

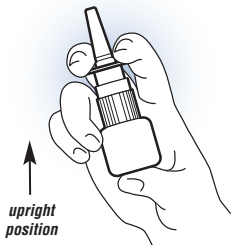
Pump. Hold the bottle on a flat surface (like a table), and screw the pump onto bottle by gripping the grooves of the pump and twisting clockwise until the pump is tightly sealed to the bottle.

Step 4. Removing Cap.

To remove the cap from the pump, twist slightly while pulling up. Save the cap to replace after each use.

Step 5. Removing the

Lock Tab. Grasp the lock tab between thumb and forefinger, while holding the bottle on a flat surface. Pull sideways to remove the tab and unlock the pump.



Step 6.

Step 6. Prime New Pump Before First Use.

Before you use a new bottle of Fortical® Nasal Spray for the first time, you will need to prime it. This will ensure you get the right dose of medicine each time you use it. After you attach the pump to the bottle, and the pump and bottle have reached room temperature, you should:

- Hold the bottle upright.
- With your index and middle fingers on each side of the top of the pump, and with your thumb under the bottle, push the pump down.
- Push the pump down at least 5 times, until you see a full spray.
- If the pump is not delivering a full spray during or after priming, contact Upsher-Smith at 1-800-654-2299. Do not place anything into the opening of the pump.

You only need to prime a new bottle. Do NOT re-prime it before each use.

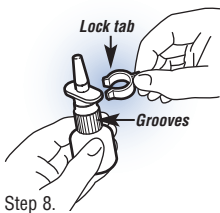
Using Fortical® Nasal Spray...



Step 7.

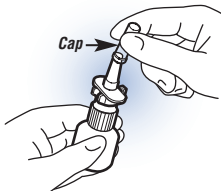
Step 7. Using Fortical® Nasal Spray

- Change (alternate) between using the right nostril one day and the left nostril the next day.
- Hold your head and the bottle in an upright, vertical position. Put the spray tip into your nostril at the same angle as your nasal passage.
- Press the pump all the way down one time. You do not need to inhale.
- If you do not hold the bottle upright during use, the pump may not be able to give you the right dose of medicine.
- You may not feel the spray because the mist is so fine. Do not waste medication by testing the sprayer. It is all right if some of the spray drips out of your nostril. One spray will give you the correct daily dose of Fortical® Nasal Spray.



Step 8.

Step 8. Replace The Lock Tab After Use. Replace the lock tab to prevent wasting medication by accidentally depressing the pump. Simply slide the lock tab on by pushing it sideways against the grooves in the pump.



Step 9.

Step 9. Replace The Cap.

- Hold the top of the pump as shown in diagram 9., and slide the cap back over the tip carefully.
- **Do NOT put the pump back in the refrigerator.**

Store Fortical[®] Nasal Spray in an upright position. Tighten the pump securely to the bottle (see Step 3 and 4 in the Patient Instructions for Use). This will help to ensure a good seal between the pump and the bottle.

Cleaning the Pump. Clean the spray tip by gently wiping it with a clean, damp cloth or tissue. Dry the tip with a cloth or tissue before replacing the cap. Do not submerge the tip or bottle in water.



Upsher-Smith Laboratories, Inc.

Minneapolis, MN USA 55447-4709

www.upsher-smith.com

Toll Free 1-800-654-2299

103001-01

Revised 0609

UPSHER-SMITH