

For postmenopausal osteoporosis

In tune with healthy
bone remodeling

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

Harmonious with bone health

What is osteoporosis?

Osteoporosis is a disease of bone loss in which bones become weaker and thinner and may fracture. Osteoporosis is characterized by low bone mass, bone fragility, and an increased risk of fractures especially at the spine, hips, and wrists.

What causes osteoporosis?

Bone is a living tissue that is constantly being broken down (*resorbed*) and rebuilt (*formed*) in a process called bone remodeling. This process has several important functions, such as freeing calcium from bone for use by the body as well as repairing tiny fractures in bone. In healthy individuals, the rates of bone resorption and formation are approximately equal.

Age-related bone thinning occurs when bone loss outpaces bone formation. Women are especially at risk for increased bone loss after menopause, which is when the ovaries stop producing estrogen. Because estrogen helps protect against bone loss, decreased production causes bones to weaken and lose density. Eventually, this bone loss may lead to an increased risk of osteoporosis.



How many people are affected by osteoporosis?

Osteoporosis is a growing public health concern. It is estimated that over 40 million Americans are affected...about 10 million have osteoporosis (80% are women). In addition, approximately 34 million Americans have low bone mass—an increased risk factor.

Is there anything I can do to help prevent osteoporosis?

A balanced diet rich in calcium and vitamin D is essential for the prevention of weakened bones later in life. Exercise helps make bones and muscles stronger, which in turn helps prevent osteoporosis and fractures. Smoking and excessive intake of alcohol should be avoided. These can interfere with the body's ability to maintain normal healthy bones. It's never too late to take steps to help prevent osteoporosis...or further bone loss, if you've already been diagnosed with the disease.



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How do I know if I have osteoporosis?

It's hard to tell if you have osteoporosis since the disease often develops and progresses without symptoms. Osteoporosis is often referred to as a silent disease.

Bones may lose strength and become weak over many years. These changes may not be noticed until a bone actually breaks. Even the slightest spontaneous movement may cause a fracture including sudden strains, bumps, and falls. Collapsed vertebrae (the bones that make up the spinal column) may first be noticed in the form of severe back pain, loss of height, or spinal deformities like kyphosis (stooped posture).

Women are more likely to get osteoporosis than men. However, there are factors besides gender that can increase the risk of osteoporosis.



Am I at risk for osteoporosis?

Answer the following questions to determine your risk for developing osteoporosis:

1. Are you Asian or Caucasian?
2. Are you a postmenopausal woman?
3. Do you have a thin/small frame?
4. Is your dietary intake of dairy products or other sources of calcium low?
5. Have you been taking thyroid medication, cortisone-like drugs for asthma or arthritis, antiseizure medications, or medication for certain cancers?
6. Have you had an early or surgically induced menopause?
7. Have you or a primary relative broken a bone as an adult?
8. Do you smoke?
9. Are you physically inactive?

The more “yes” answers you have, the greater your risk.

Are there any medications that can help?

If you have been diagnosed with osteoporosis there are medications your doctor can prescribe that can help. Osteoporosis treatments can help slow bone loss and increase bone mass. Your doctor will know which one is best for you.

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Fortical[®] Nasal Spray is an effective option for treatment of postmenopausal osteoporosis

Fortical[®] is a nasal spray for the treatment of postmenopausal osteoporosis in women greater than 5 years after menopause with low bone mass relative to healthy premenopausal women. Fortical[®] Nasal Spray is available by prescription only. Fortical[®] Nasal Spray should be taken along with adequate calcium and vitamin D every day.

Calcitonin-salmon is the active ingredient in Fortical[®] Nasal Spray and is involved in calcium regulation and bone remodeling.¹ Fortical[®] Nasal Spray helps stop bone loss, and helps build bone.

Safely treats postmenopausal osteoporosis with no significant drug-related side effects

- No known drug interactions
- Most side effects were mild to moderate in severity
- No reported drug-related hot flashes or leg cramps



Ask your doctor if Fortical® Nasal Spray is right for you

The most commonly reported side effects are rhinitis (runny nose), other nasal symptoms, back pain, arthralgia (joint pain), epistaxis (nosebleed), and headache. Periodic nasal examinations are recommended; if nasal ulceration occurs, discontinue treatment until healed.

Talk to your doctor about any side effects you may have while taking Fortical® Nasal Spray. He or she may recommend that you briefly stop using Fortical® Nasal Spray until certain symptoms go away.

Fortical® Nasal Spray contains calcitonin-salmon (a protein), therefore the risk of an allergic reaction exists. You should not take Fortical® Nasal Spray if you are allergic to calcitonin-salmon.

Fits right in with your normal routine

- No waiting with regard to eating or drinking
- No need to stand or remain upright after dosing
- Bedtime dosing is an option
- Just one spray daily, any time of day, with or without food

Please see Fortical® Nasal Spray assembly and usage instructions and important patient information on the following pages.

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

Harmonious with bone health

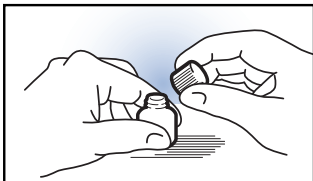
Fortical[®] calcitonin-salmon (rDNA origin) Nasal Spray

Assembly
and Usage
Instructions

Easy-To-Use Fortical[®] Nasal Spray

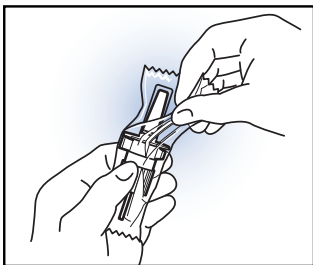
IMPORTANT:

- Keep sealed bottle in refrigerator (36-46°F) until opened. Do NOT Freeze.
- Allow Fortical[®] Nasal Spray to reach room temperature before first use.
- After opening – store at room temperature, 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F).
- Store unit in an upright position and tighten the pump securely to the bottle (see Step 3 and 4 for instructions). Upright storage and a properly tightened pump will help to ensure a proper seal between the pump and the bottle.
- Fortical[®] Nasal Spray remains effective up to 30 days from the time it is opened. After 30 days, it should be discarded. **Discard 30 days after first use.**

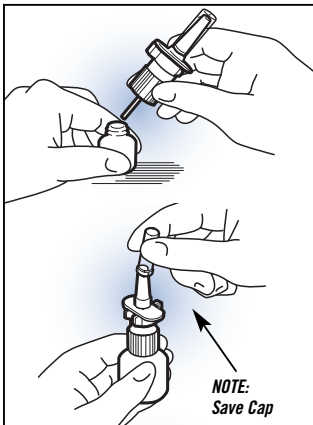


Assembly Instructions

1. Opening the Bottle. If your pharmacist attached the pump for you, skip to step 4. Otherwise, set bottle on table or counter top, and hold firmly while unscrewing cap to avoid spilling any Fortical[®] Nasal Spray.

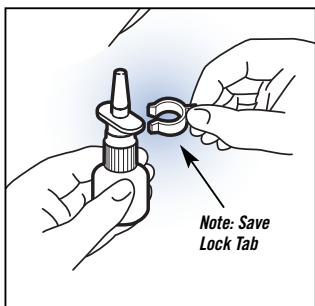


2. Unwrapping the Pump. Carefully cut shrink wrap with scissors or knife, and tear away from pump, being careful not to bend or contaminate feed tube at bottom.



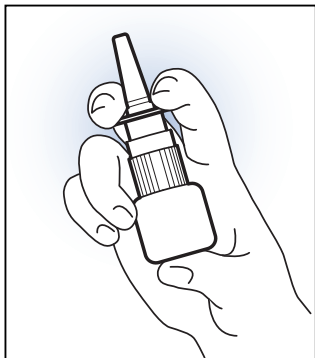
3. Attaching the Pump. Holding bottle on a flat surface (like a table), screw pump onto bottle by gripping the grooves of the pump and twisting clockwise until the pump is tightly sealed to the bottle.

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



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

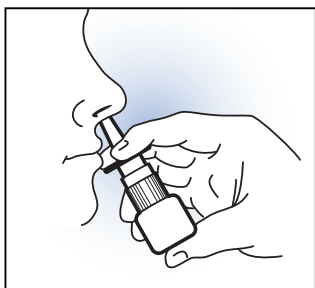
Save the lock tab, and push it back onto the pump after each use to avoid accidentally wasting any Fortical® Nasal Spray



6. Prime New Pump Before First Use.

To ensure the proper dose, you need to prime the new pump after attaching it to the bottle once the pump and bottle have reached room temperature. Hold the bottle upright. With your index and middle fingers on each side of the top of the pump, and your thumb under the bottle, push the pump down. Repeat until you see a full spray, which may take up to 5-7 depressions. If the pump is not delivering a full spray during or after priming, contact Upsher-Smith at the phone number referenced on the back of these instructions. Do not place anything into the opening of the pump.

Once the new pump is primed, it is NOT necessary to re-prime it before each use.



Using Fortical® Nasal Spray...

Fortical® Nasal Spray is easy to use. One spray into one nostril once a day delivers your recommended daily dose.

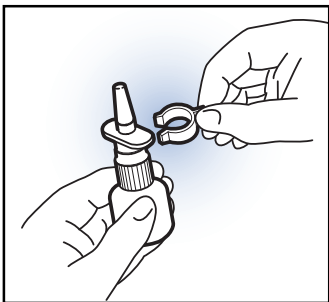
You can spray Fortical® Nasal Spray into either nostril. Simply hold your head and the unit in an upright, vertical position, and place the spray tip into your nostril at the same angle as your nasal passage. Then press the pump all the way down one time. You do not need to inhale. If the unit is not held upright during use,

the pump may not be able to deliver an accurate dose.

You may not feel the spray, because the mist is so fine. But do not waste medication by testing the sprayer. It is all right if some of the spray drips out of your nostril. Just one spray will give you the correct dose.

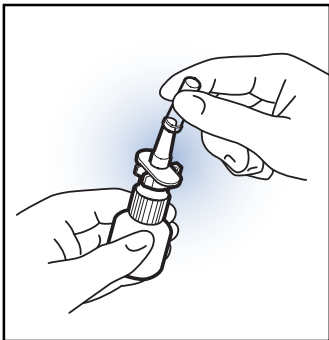
Alternate Nostrils. We suggest you not spray Fortical® Nasal Spray into the same nostril each day. Instead, use the right nostril one day, and the left nostril the next day.

Use Fortical® Nasal Spray Every Day. A single spray each day delivers 200 International Units of calcitonin-salmon. Supplemental calcium and vitamin D should be taken as directed by your health care provider. Together, they offer an alternative to help defend against postmenopausal osteoporosis. Each bottle of Fortical® Nasal Spray contains enough doses to last approximately 30 days.



7. Replace The Lock Tab After Use.

Replacing the lock tab can prevent wasting medication by accidentally depressing the pump. Simply slide the lock tab on by pushing it sideways against the grooves in the pump.



8. **Replace The Cap.** Slide the cap back over the spray tip carefully, while holding the top of the pump.

Do NOT return the bottle to the refrigerator. After priming the pump, store Fortical® Nasal Spray in an upright position at room temperature, 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F). Discard 30 days after first use.

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

PATIENT INFORMATION:

What you should know about Fortical® calcitonin-salmon (rDNA origin) Nasal Spray

What is Fortical® Nasal Spray? Fortical® Nasal Spray is used to treat osteoporosis in postmenopausal women with low bone mass.

What does Fortical® Nasal Spray do? Fortical® Nasal Spray contains calcitonin, a scientifically-engineered protein that is similar to a natural protein found in the human body. The precise way this protein works is still being studied. But it is generally understood that calcitonin slows down the activity of osteoclasts (the cells that remove old bone material). Reducing the amount of old bone material that is removed, while new bone building continues, results in increased bone mass.

Why is Fortical® a nasal spray? It is both convenient and easy to use. It is also an effective way to quickly get Fortical® Nasal Spray into your blood stream. It is easily absorbed into the blood vessels lining your nasal passage.

Is Fortical® Nasal Spray a substitute for calcium supplements? No. Fortical® Nasal Spray is not a source of calcium. It works with the calcium and vitamin D supplements recommended by your doctor, and can help you gain maximum benefit from calcium replacement therapy. It is important to take all of the calcium and vitamin D supplements your doctor directs each day.

How much calcium does my body need each day? This 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. If you are not getting enough calcium in your daily diet, your doctor may recommend a calcium supplement.

Vitamin D is necessary for your body to process calcium to build bone material. That is why your doctor may have recommended that you add a vitamin D supplement to your diet.

Why is osteoporosis a greater concern after menopause? Following menopause, the amount of estrogen produced by a woman's body dramatically decreases. Estrogen helps balance bone growth and keep bones strong. When it is reduced, your body may remove old bone cells faster than it replaces them with new bone cells. As a result, bones can become weak and brittle, and more susceptible to fractures. This condition is known as postmenopausal osteoporosis.

What are the dangers of postmenopausal osteoporosis? In addition to broken wrists, hips and other bones – postmenopausal osteoporosis can lead to a curved spine, rounded shoulders and even loss of height. It can be a painful, disabling condition.

That is why your doctor has recommended Fortical® Nasal Spray to help protect against this condition.

How much Fortical® Nasal Spray should I use each day? A single spray into either nostril will deliver the correct daily dose of Fortical® Nasal Spray (200 International Units of calcitonin-salmon in a 0.09 mL solution).

Is age a concern? Fortical® Nasal Spray can be used at any age. No unusual side effects or any increase in other side effects have been reported for elderly patients.

Is there any reason a person should not use Fortical® Nasal Spray? This product should not be used by anyone who is allergic to the calcitonin-salmon protein, or pregnant or nursing women.

Why is Fortical® Nasal Spray in a brown bottle? Some of the components of the formulation of Fortical® Nasal Spray are sensitive to light. To maintain the product's stability, amber glass is required to avoid direct exposure to light.

Other warnings and precautions. While no formal studies have been completed to test drug interaction with calcitonin-salmon, there are no known drug interactions. As usual, however, you should tell your doctor and pharmacist what other prescription and non-prescription medications you are taking.

A nasal exam should be completed before using this medication and if you experience nasal discomfort while using it. In clinical studies, nasal irritation occurred in approximately 6% of participants.

As with any protein, some people may have a systemic allergic reaction to calcitonin-salmon. If you are allergic to the calcitonin-salmon protein, you should not use this product.

Please be aware that using Fortical® Nasal Spray directly from a refrigerator without being warmed to room temperature may cause local discomfort.

Possible side effects. Most patients do not experience any side effects with Fortical® Nasal Spray. As with any medication, however, some people may notice some side effects. These side effects are usually mild, and do not cause patients to discontinue treatment.

The most common side effects include: nasal symptoms (such as runny nose, crusting or nosebleed), back and/or joint pain and headache.

If you have any questions, concerns or unusual symptoms, contact your doctor.

This medication is intended for a particular condition. Do not use it to treat any other condition, or give it to others.

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

Upsher-Smith Laboratories, Inc.

Minneapolis, MN USA 55447-4709

www.upsher-smith.com

Toll Free 1-800-654-2299

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UPSHER-SMITH

Pharmaceuticals Since 1919

Fortical[®] Nasal Spray is harmonious with bone health

- Complements healthy bone remodeling
- Fits right in with your normal routine
- Provides a cost-effective bone building option

*Ask your doctor if
Fortical[®] Nasal Spray
is right for you*

www.fortical.com

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

Harmonious with bone health

Reference: 1. Fortical[®] calcitonin-salmon (rDNA origin)
Nasal Spray product information.

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