

Information for the Patient

Miacalcin®

(calcitonin-salmon)

Nasal Spray

What is MIACALCIN® [MEE-uh-KAL-sin] Nasal Spray?

MIACALCIN® Nasal Spray is a medication used for the treatment of osteoporosis after menopause (postmenopausal osteoporosis) in women more than 5 years after menopause with low bone mass who refuse or cannot tolerate estrogens, or in whom estrogens are not an option. Patients who use MIACALCIN® Nasal Spray should be sure to ingest adequate amounts of calcium and vitamin D along with therapy.

How much calcium and vitamin D do I need each day?

When taking MIACALCIN® Nasal Spray, it is recommended that you get at least 1000 mg of calcium and 400 I.U. (International Units) of vitamin D each day. Check with your doctor or healthcare provider to see if you are getting enough calcium and vitamin D in your diet. If not, he or she may recommend that you start taking calcium and vitamin D supplements.

What is osteoporosis after menopause? What causes it?

Postmenopausal osteoporosis is a condition associated with frail, brittle bones. It usually occurs when “old” bone cells are removed from bones faster than they can be replaced by “new” bone cells. As a result, bones get weak and may become susceptible to fractures.

Osteoporosis occurs most frequently in women who have gone through menopause. At menopause, a woman’s body goes through many changes, including a substantial decrease in the amount of estrogen produced. Estrogen in your body helps keep bones strong -- without it, they may become weak.

Postmenopausal osteoporosis begins without notice; however, over time symptoms develop such as:

- Curved spine
- Rounded shoulders
- Loss of height

Untreated, postmenopausal osteoporosis can be painful and disabling. Some women with postmenopausal osteoporosis suffer from broken hips and fractured wrists. Fortunately, osteoporosis after menopause is treatable. Your doctor or healthcare provider can prescribe a medication, like MIACALCIN® Nasal Spray, to treat your condition.

How does MIACALCIN® Nasal Spray work?

The active ingredient in MIACALCIN® Nasal Spray is calcitonin, a man-made protein similar to one found in people, other mammals, and some types of fish and birds.

The way calcitonin affects bone is still being studied, but it is believed to work in the following ways:

- Calcitonin reduces the activity of osteoclasts [AHS-tee-oh-clasts], the cells that remove “old” bone
- Because bone building continues while bone removal is slowed down, the result is an increase in bone mass

When you spray MIACALCIN® 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 works to stop bone loss and helps your bones become stronger.

How do I use MIACALCIN[®] Nasal Spray?

The recommended dose of MIACALCIN[®] Nasal Spray is one spray daily in alternated nostrils -- unless directed otherwise by your healthcare provider. Start with a spray in the left nostril on your first day, followed by a spray in the right nostril on the second day. Continue to alternate nostrils every day. There are at least 30 “doses” of MIACALCIN[®] Nasal Spray in each bottle.

You should keep track of the number of doses used from the bottle.

After 30 doses, each spray may not deliver the correct amount of medication, even if the bottle is not completely empty.

Who should not take MIACALCIN[®] Nasal Spray?

MIACALCIN[®] Nasal Spray should not be used by patients who are allergic to the protein calcitonin-salmon, or by women who are pregnant or nursing.

You should be aware of these warnings and precautions when taking MIACALCIN[®] (calcitonin-salmon) Nasal Spray.

- No formal studies designed to test drug interactions with calcitonin-salmon have been done; however, no drug interactions have been observed with the use of MIACALCIN[®] Nasal Spray. You should inform your doctor and pharmacist about the other prescription and nonprescription medications you are taking.
- In clinical studies, nasal symptoms occurred in approximately 9% of postmenopausal patients taking MIACALCIN[®] Nasal Spray. For this reason, it is recommended that a nasal examination be performed prior to the start of treatment and at any time nasal complaints occur.
- Rare instances of nasal ulceration have occurred with MIACALCIN[®] Nasal Spray. In some cases, your doctor may decide to temporarily discontinue treatment with MIACALCIN[®] Nasal Spray until symptoms subside.
- Because calcitonin-salmon is a protein, the possibility of a systemic allergic reaction exists. Patients who are allergic to calcitonin-salmon should not use MIACALCIN[®] Nasal Spray.
- MIACALCIN[®] Nasal Spray is safe to use in elderly patients. A slight increase in nasal symptoms has been observed in patients over 65 years of age, however the symptoms are usually mild. No other unusual side effects have been seen in patients over 65 years of age.

Possible side effects

Most patients tolerate treatment with MIACALCIN[®] Nasal Spray very well; however, like all prescription drugs, MIACALCIN[®] Nasal Spray may cause some side effects in some people. These side effects are usually mild and generally do not lead to discontinuation of treatment with MIACALCIN[®] Nasal Spray. The most commonly reported side effects are:

- Nasal symptoms such as runny nose, crusting, or nasal bleeding
- Back/joint pain
- Headache

Anytime you have a medical problem you think may be related to MIACALCIN[®] Nasal Spray, talk to your doctor or healthcare provider.

Your doctor or pharmacist can demonstrate how to assemble, prime, and use MIACALCIN[®] Nasal Spray. In addition, detailed directions can be found in your MIACALCIN[®] Nasal Spray box. Please read them carefully before assembling and using the spray.

This medication is prescribed for a particular condition. Do not use it for another condition or give the drug to others. Keep MIACALCIN[®] Nasal Spray and all medicines out of reach of children. This leaflet provides a summary of information about MIACALCIN[®] Nasal Spray. If you have any questions or concerns about either MIACALCIN[®] Nasal Spray or osteoporosis, talk to your doctor. In addition, talk to your pharmacist or other healthcare provider.



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HOW TO ASSEMBLE AND USE

Miacalcin[®] NASAL SPRAY



(calcitonin-salmon) Nasal Solution

ONE SPRAY, ONCE A DAY

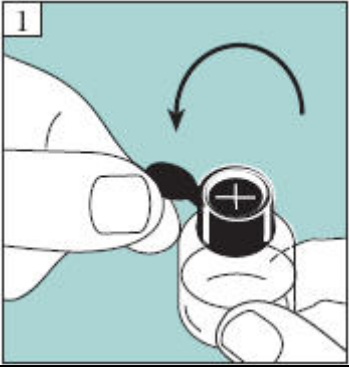
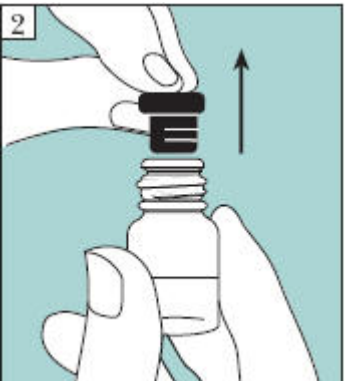
BEFORE USING MIACALCIN[®] (calcitonin-salmon) NASAL SPRAY

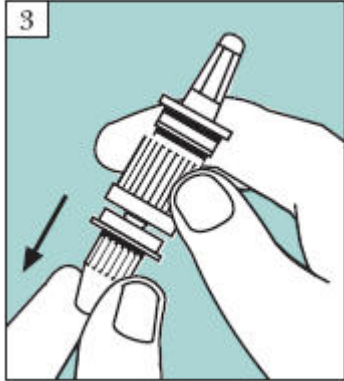
This package contains one bottle of MIACALCIN[®] (calcitonin-salmon) Nasal Spray and one screw-on pump.

Important Facts About Your Medication:

- The bottle contains the proper amount of medication — be aware that the entire bottle will not be filled with liquid.
- Before opening and assembling your medication bottle, keep it in your refrigerator between 2°C-8°C (36°F-46°F). Do not freeze.
- After opening and assembling a new medication bottle, keep it at room temperature between 15°C-30°C (59°F-86°F) in an upright position.

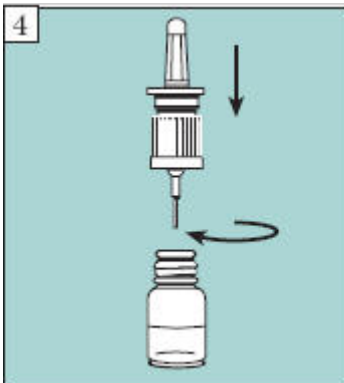
HOW TO USE MIACALCIN[®] (calcitonin-salmon) NASAL SPRAY

<p>Putting the Nasal Spray Pump Unit Together</p> 	<p>1. If your bottle and pump unit were already assembled by your pharmacist, go to Step 6. If not, remove the bottle from your refrigerator and allow it to reach room temperature before assembling. Lift up the blue plastic tab and carefully pull the metal safety seal off the bottle.</p>
	<p>2. Keeping the bottle upright, remove the rubber stopper from the bottle.</p>

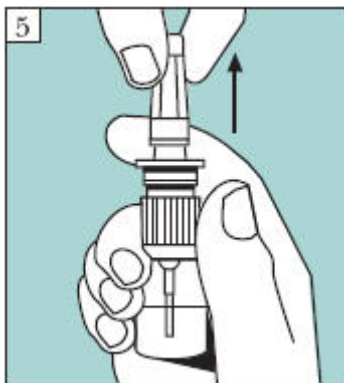


3. Holding the pump unit, gently remove the opaque plastic protective cap from the bottom of the unit.

Note: Do not depress pump when it is not attached to the bottle.

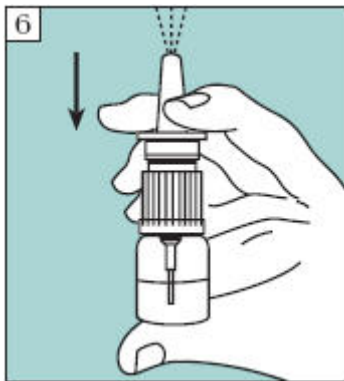


4. Holding the bottle upright, insert the nasal spray pump unit into the bottle. Then turn the pump clockwise, and tighten it until it is securely fastened to the bottle.



5. Holding the bottle upright with your index finger on top of one of the two side arms of the pump, gently remove the clear protective cap from the top of the nozzle.

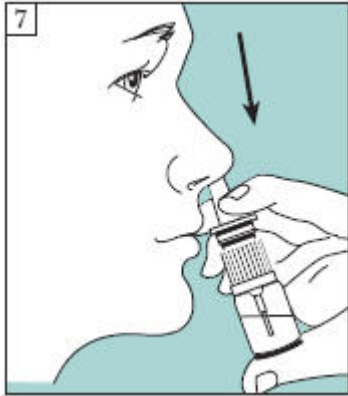
Priming a New Bottle



6. **To ensure proper delivery of medication, a newly opened and assembled bottle must be primed before you use it for the first time. If your pharmacist assembled the unit for you, check to see if it has already been primed by pumping the unit once. If a full spray is emitted, the unit has already been primed. If no spray is emitted, you must prime the unit. Holding the bottle upright with your index and middle fingers on the two side arms of the pump, and your thumb on the bottom of the bottle, press the arms down fully **until you see a full spray**. Now the nasal spray is ready for use.**

Do not re-prime the pump before each daily use because this will waste your medication.

Using the Medication



7. The recommended dose of MIACALCIN® (calcitonin-salmon) Nasal Spray is one spray once a day in one nostril.

Keep your head upright and carefully place the nozzle in one nostril.

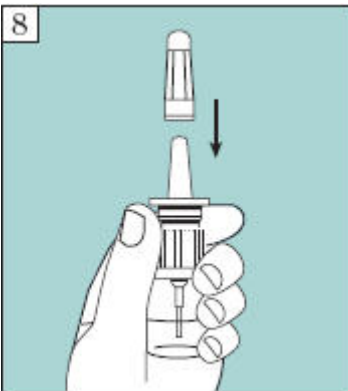
Tilt the bottle until it is in a straight line with the nasal passage.

Firmly press down on the pump once to spray the medication into your nose. It is not necessary to inhale while this is being done. Please note: Because the mist is so fine, you may not feel it inside your nose. Also, some medication may drip out of your nose. However, in either case, the medication is absorbed. **IMPORTANT:** Do not “test” the spray unit or prime it before you use your daily dose because this will waste your medication.

Cleaning the Pump

Once or twice a week, wipe the nozzle with a clean, damp cloth. Dry the nozzle before replacing the clear protective cap.

Storing the Unit



8. Holding the bottle with two fingers **under** the two side arms of the pump, gently replace the protective cap on the nasal spray unit. **Be careful not to depress the pump** while this is being done. Once the pump is primed, the unit must be kept at room temperature between 15°C-30°C (59°F-86°F) in the upright position until the medication is finished.

IMPORTANT

- Do not refrigerate the unit between doses.
- Do not store the unit on its side.

Bottles left at room temperature (opened or unopened) for more than 35 days must be discarded.

Refrigerated bottles are good until the expiration date stamped on the bottle and box.

Alternate Nostrils Daily

The first day, start with one spray in the left nostril. The next day, use one spray in the right nostril, and so on.

It is important to receive the correct daily amount of calcium and vitamin D, as directed by your healthcare provider.

IMPORTANT

- **Use MIACALCIN[®] (calcitonin-salmon) Nasal Spray daily.**

To ensure proper treatment, it is important to use your MIACALCIN[®] (calcitonin-salmon) Nasal Spray daily even if you have no symptoms of postmenopausal osteoporosis.

What is the Correct Dose of MIACALCIN[®] (calcitonin-salmon) Nasal Spray?

A single spray of MIACALCIN[®] (calcitonin-salmon) Nasal Spray contains one daily dose, which is 200 I.U. of calcitonin-salmon. The fine mist is actually 0.09 mL (milliliter) of solution. Your bottle of MIACALCIN[®] Nasal Spray contains at least 30 doses. Priming the pump as described in Step 6 does not alter the total number of doses available in a bottle of MIACALCIN[®] Nasal Spray. The bottle need only be primed once after assembly. Do not re-prime or “test spray” your bottle before you use your daily dose of MIACALCIN[®] Nasal Spray. This will waste your medication.

For more information on MIACALCIN[®] Nasal Spray and how to assemble it, please call Novartis Pharmaceutical Corporation at 1-888-669-6682.

Please see your healthcare provider for complete product information for MIACALCIN[®] Nasal Spray.

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