



Package leaflet: Information for the user

Miacalcic®

200 IU nasal spray, solution
Calcitonin (salmon, synthetic)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Miacalcic nasal spray is and what it is used for
2. What you need to know before you use Miacalcic nasal spray
3. How to use Miacalcic nasal spray
4. Possible side effects
5. How to store Miacalcic nasal spray
6. Contents of the pack and other information

1. What Miacalcic nasal spray is and what it is used for

Miacalcic nasal spray contains the active substance calcitonin (salmon, synthetic).
Calcitonin is a hormone that occurs naturally in the body of

both humans and animals. It regulates the level of calcium in the blood. Calcitonin is used to reverse bone loss and may also help in bone formation.

Miacalcic nasal spray is used to treat osteoporosis (thin and weak bones) in women after the menopause to reduce the risk of spinal fractures.

2. What you need to know before you use Miacalcic nasal spray

Do not use Miacalcic nasal spray

- if you are **allergic** to calcitonin (salmon, synthetic) or any of the other ingredients of this medicine (listed in section 6);
- if you have a **very low calcium level** in your blood (hypocalcaemia).

Warning and precautions

Before treatment with Miacalcic nasal spray tell your doctor if you suspect you may be allergic to calcitonin (salmon, synthetic). Your doctor will perform a **skin test** before you start using Miacalcic nasal spray.

If you have a sore nose, do not start using Miacalcic nasal spray. Tell your doctor who will examine your nose before you start using Miacalcic nasal spray.

Children and adolescents (age under 18 years)

Use of Miacalcic is not recommended in patients under 18 years of age.

Older people

Miacalcic nasal spray can be used by older patients without any special requirements.

Other medicines and Miacalcic nasal spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is

particularly important to tell your doctor if you are taking a medicine containing lithium, as the dose of lithium may need to be changed.

Pregnancy and breast-feeding

Miacalcic nasal spray should not be used in pregnant or breast-feeding women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Miacalcic nasal spray may cause tiredness, dizziness and disturbed vision which could affect your reactions. If this happens to you, do not drive or use any machines.

Miacalcic nasal spray contains benzalkonium chloride

Miacalcic nasal spray contains benzalkonium chloride, which can cause swelling of the inside of your nose, especially with longterm use. If you notice any nasal congestion, contact your doctor. Your doctor may decide to prescribe another treatment for you.

3. How to take Miacalcic nasal spray

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. This medicine is for nasal use only.

Your pharmacist has stored Miacalcic nasal spray in a refrigerator. Before you start using it, you should let the spray reach room temperature. You should store Miacalcic nasal spray at room temperature.

The **usual dose** is one spray puff (200 IU) daily. It is recommended that you administer Miacalcic nasal spray to alternating nostrils.

It is recommended that you also take an adequate amount of

calcium and vitamin D whilst using Miacalcic nasal spray. Ask your doctor for advice.

Before the nasal spray is used for the first time, the pump must be primed as described below in the “Instructions for use of Miacalcic nasal spray”. The instructions should be followed carefully.

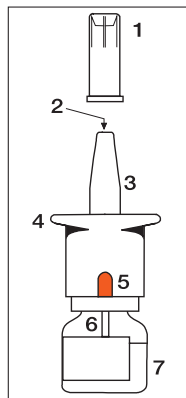
Instructions for use of Miacalcic nasal spray


Please read the instructions carefully so that you know how to use your nasal spray. These instructions tell you about:

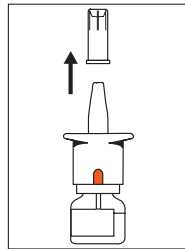
- A. The different parts of your nasal spray.
- B. How to prepare a new nasal spray for use.
- C. Using the nasal spray.
- D. Checking the counter


Always follow your doctor’s instructions regarding dose carefully.

A. The different parts of the spray bottle

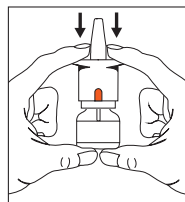


1. **Protective cap:** Keeps the nozzle clean and protects the jet. Always replace the protective cap after you have used the nasal spray.
2. **Jet:** The tiny hole from which the medicine sprays out.
3. **Nozzle:** The part you insert into your nostril.
4. **Pump:** The part you press down to operate the spray.
5. **Counter:** The dose counter window on a new nasal spray shows , as shown in the picture. The display will change as you use the pump (see below).



The dose counter window of a new nasal spray bottle is in the position marked  in the picture.

- First, remove the protective cap.

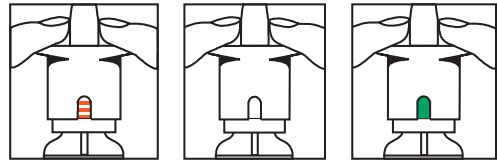


- Hold the nasal spray upright in one or two hands and press down firmly on the pump **3 times**. This primes the new spray by clearing the air out of the dip tube. You will only need to do this once when you start a **new** spray. Do not worry if a little medicine sprays out; this is normal.

6. **Dip tube:** The tube inside the spray bottle that draws up the medicine when you press the pump.
7. **Bottle:** Contains enough medicine for at least 14 metered doses.

B. Preparing a new nasal spray bottle for use:

- **NEVER** shake the nasal spray bottle as this could cause air bubbles which may affect your dose.



As you press the pump, watch the changes in the dose counter window:



- When the green is showing in the dose counter window, your new nasal spray is ready to use.
- Follow the instructions for “Using your spray”.

C. Using your nasal spray

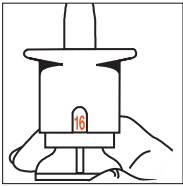


- After removing the protective cap, bend your head forward slightly and insert the nozzle into one of your nostrils. Try to hold the nasal spray upright, as shown in the picture.
- Press the pump firmly **only once**.
- Remove the nasal spray from your nose and breathe in deeply through your nostril to help keep the medicine in your nose.
- If your doctor has told you to take two puffs at a time, repeat this procedure in your other nostril.
- After use, clean the nozzle with a dry tissue and replace the protective cap.

D. Checking the counter

Every time you use the nasal spray the number in the dose counter window will change. The number displayed tells you how many puffs you have already taken. The Nasal Spray is guaranteed to deliver 14 metered doses. You may be able to obtain 2 additional doses.

When the dose counter window turns red and displays the number (16), as shown in this picture you have taken 16 spray puffs and the spray is finished. You may notice that a little liquid is left in the nasal spray bottle, but this is normal.



If the spray mechanism becomes blocked, this may be fixed by pressing the pump forcefully; **do not** attempt to unblock it using a sharp pointed object as this may cause damage. If you think your nasal spray is not working properly, return it to your supplier. Never try to fix the nasal spray yourself or take it apart, as this may affect your dose.

If you use more Miacalcic nasal spray than you should

If you have accidentally taken too much Miacalcic nasal spray, tell your **doctor immediately**. You may require medical attention.

If you forget to use Miacalcic nasal spray

If you forget to use your nasal spray, take the spray as soon as you remember unless it is less than 4 hours before the next dose. If so, wait and take your next dose at the usual time. Do not take a double dose to make up for a forgotten one. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most frequently observed side effects are those affecting the nose such as sore nose and runny or stuffy nose. These are generally mild and rarely require the treatment to be stopped.

Some side effects could be serious:

- Increased heartbeat, nettle rash (hives), difficulty breathing, swelling of the tongue and throat, tightness in your chest, a sudden fall in blood pressure or shock. These may be signs of a severe allergic reaction (anaphylaxis) and are very rare.
- Swelling of your face, limbs or entire body (uncommon).

If you experience any of these, contact a doctor immediately.

Other side effects:

- Very Common side effects** (may affect more than 1 in 10 people):
- Sore nose, runny or stuffy nose (rhinitis), swelling, redness and damage to the inside of the nose, sneezing, dry nose, nasal allergies, irritated nose, unpleasant smell.

Common side effects (may affect up to 1 in 10 people):

- diarrhoea, stomach pain, feeling sick,
- tiredness,
- pain in bone or joints,
- dizziness,
- headache,
- changes in the way things taste,
- sudden waves of redness of the face and/or neck (flush),
- nose bleed,

- feeling of pressure or pain in nose, cheeks and behind eyes (inflammation of the sinuses), nasal inflammation and damage,
- sore throat and discomfort when swallowing (pharyngitis).

Uncommon side effects (may affect up to 1 in 100 people):

- high blood pressure (hypertension),
- flu-like symptoms,
- disturbed vision,
- allergic reactions,
- cough,
- being sick,
- itching.

Rare side effects (may affect up to 1 in 1,000 people):

- Skin rash.

Not known (frequency cannot be estimated from the available data):
Trembling

In rare cases the effectiveness of Miacalcic may be reduced.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Miacalcic nasal spray

Keep out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C–8°C). Do not freeze.
Once opened, the nasal spray must be kept at room temperature (not above 25°C).
The nasal spray must be used within 1 month after opening.

Keep the bottle upright at all times to reduce the risk of air bubbles getting into the dip tube.
Do not shake the bottle.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Miacalcic nasal spray contains

- The active substance is calcitonin (salmon, synthetic). Each 2 ml bottle of Miacalcic nasal spray contains at least 14 metered doses of 200 IU. One IU (International Unit) corresponds to 0.167 micrograms of calcitonin (salmon, synthetic).
- The other ingredients are benzalkonium chloride (as a preservative), sodium chloride, hydrochloric acid and water.

What Miacalcic nasal spray looks like and contents of the pack

Miacalcic 200 IU is a nasal spray, solution (nasal spray).

Miacalcic 200 IU nasal spray is available in packs of one or three bottle(s) of 2 ml.
Not all strengths and pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer
Novartis Pharmaceuticals UK Ltd, trading as
Sandoz Pharmaceuticals, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, England.

Miacalcic nasal spray is released onto the market by Novartis Pharmaceuticals UK Ltd, Wimbleshurst Road, Horsham, West Sussex RH12 5AB, United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Calcitonin “Novartis”
Belgium	Miacalcic
Ireland	Miacalcic

This leaflet was last revised in April 2012.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, tel. 01276 698370.

Miacalcic is a registered trade mark