

# MIACALCIC<sup>®</sup> NASAL SPRAY

Synthetic salmon calcitonin (200 IU)

## What is in this leaflet:

1. What Miacalcic Nasal Spray is used for
2. How Miacalcic Nasal Spray works
3. Before you use Miacalcic Nasal Spray
4. How to use Miacalcic Nasal Spray
5. While you are using it
6. Side effects
7. Storage and Disposal of Miacalcic Nasal Spray
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Miacalcic Nasal Spray is used for

Miacalcic Nasal Spray is indicated for the treatment of:

- *Prevention of osteoporosis (brittle bones):* In acute bone loss due to sudden immobilisation such as in people with osteoporotic fractures. Miacalcic should be supplemented with adequate doses of calcium and vitamin D, as needed by the individual, to prevent further loss of bone mass. The maximum duration of treatment is 3 months.
- *Paget's disease (osteitis deformans), a slowly progressing illness which can cause a change in the size and shape of certain bones:* Only in people who do not respond to alternative treatments or for whom alternative treatments are not suitable: The duration of treatment is normally 3 months.
- *Algodystrophy or Sudeck's disease (neurodystrophic disorders):* Neurodystrophic disorders (pain and swelling occurring after injury, trauma or burn) due to various causes and predisposing factors such as posttraumatic painful osteoporosis, reflex dystrophy, shoulder-arm syndrome, causalgia and drug-induced nerve disorders. The duration of treatment is up to 6 weeks.

## How Miacalcic Nasal Spray works

The active substance of Miacalcic belongs to a group of substances

known as calcitonins. Calcitonin is a hormone that occurs naturally in the bodies of both humans and animals. Calcitonin regulates the level of calcium in the blood. It is used to reverse bone loss and it is thought that it may also help in bone formation. Synthetic salmon calcitonin, the active substance of Miacalcic, is a potent and long acting form of this hormone. Miacalcic inhibits increased bone loss due to illness. In certain cases, it also has an analgesic effect.

## Before you use Miacalcic Nasal Spray

### - When you must not use it

Do not take Miacalcic Nasal Spray if you are allergic (hypersensitive) to salmon calcitonin, or to any of the other ingredients listed at the end of this leaflet (see section **Product description**).

### **Pregnancy and breast-feeding**

You should tell your doctor if you are pregnant or think that you may be pregnant. Miacalcic should be used with caution during pregnancy.

Breast-feeding during treatment is not recommended.

### - Before you start to use it

Using Miacalcic has risks which should be taken into account when deciding to start or continue treatment. Tell your doctor or pharmacist if you:

- suffer from any other diseases,
- have any allergies, or
- Are taking or externally applying any other medicines (including those bought without a prescription).

### - Taking other medicines

**Tell your doctor or pharmacist** if you are taking or have recently taken any other medicine. Remember also those not prescribed by a doctor.

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

## How to use Miacalcic Nasal Spray

### - How much to use

*Prevention of osteoporosis*

200 IU (1 metered dose of Miacalcic 200) daily, if necessary in several divided doses.

### *Paget's disease*

In Paget's disease, the recommended dose is 200 IU daily in two divided doses. In a few cases, 200 IU twice daily may be necessary at the beginning of therapy. Dose reduction may also be attempted during the course of treatment in patient using this dosage form.

### *Algodystrophy (neurodystrophic disorders)*

The recommended dose is 200 IU daily in 2 divided doses for 2-4 weeks. Thereafter, 200 IU may be used three times a week for up to 6 weeks, depending on the individual's clinical response.

There is no long-term data on using Miacalcic in children. The doctor should decide whether it is absolutely necessary to carry out treatment for longer than a few weeks.

Elderly or people with impaired liver or kidney function are given the same dose and the tolerability is the same. Treatment with calcitonin in all indications should be limited to the shortest period of time possible and using the lowest effective dose.

### - When to use it

#### *How to use Miacalcic Nasal Spray*

This medicine is for administration into the nostrils only. You should switch between each nostril every time you use Miacalcic Nasal Spray. Your pharmacist has stored Miacalcic Nasal Spray in a refrigerator. Before you start using it, you should let the spray reach room temperature.

- Please refer to '**Information for Consumers**' at the end of this leaflet for instructions for use/handling of Miacalcic Nasal Spray.

Since Miacalcic is not absorbed by the body through the digestive system, but through the nasal mucosa, it makes no difference if the medicine is taken before or after meal times.

### - How long to use it

Do not use more Miacalcic than advised by your doctor.

Your doctor will tell you exactly how long you need to use Miacalcic Nasal Spray.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you have accidentally taken too much Miacalcic, tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention.

**While you are using Miacalcic Nasal Spray**

- Things you must do

Using Miacalcic has risks which should be taken into account when deciding to start or continue treatment.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Miacalcic Nasal Spray.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking Miacalcic unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Miacalcic to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

**Driving and using machines**

This medicine may affect your reactions, and your ability to drive or to use machines or tools.

Miacalcic may cause transient fatigue, dizziness and visual disturbances, which may impair your reactions. If you experience any of these side effects, you must not drive or use machines.

**Side effects**

In very rare cases, local or general hypersensitivity reactions (skin rash, breathing difficulties, etc.) may occur. Tell your doctor in such cases and he/she will decide whether Miacalcic treatment should be stopped.

Like all medicines, Miacalcic Nasal Spray can cause side effects, although not everybody gets them. You may experience the following side effects if you use Miacalcic:

*At the site of application:*

*Very common:* Rhinitis (including dry nose, nasal swelling or congestion, sneezing, allergic rhinitis), non-specific nasal symptoms (e.g. discomfort, odour, irritation, abrasions).

*Common:* Sinus inflammation and lesions of the mucous membrane, nose bleed.

*Side effects affecting the whole body*

*Common:* flushing (sudden waves of redness of the face and/or neck), headache, dizziness, nausea, diarrhoea, abdominal pain, joint pain, sore throat, fatigue, taste disturbance.

*Uncommon:* High blood pressure, vomiting, muscle pain, cough, flu-like symptoms, swelling (of the face, the arms and legs or of the whole body), changes in vision.

*Rare:* Hypersensitivity reactions, itching, skin rash.

Tremor was also observed in the post-marketing phase.

In clinical studies on long-term use of Calcitonin, a slight increase in the risk of cancer was observed.

If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and disposal of Miacalcic**

- Storage

- Keep out of the reach and sight of children.
- Miacalcic Nasal Spray must be stored in a refrigerator (2-8°C). Do not freeze.
- Once opened, they must be kept at room temperature (not above

25°C) and used within a maximum of 4 weeks.

- You should not use the spray if the bottle has been opened for 4 weeks or more.
- Keep the bottle upright at all times to reduce the risk of air bubbles entering the dip tube.
- Miacalcic Nasal Spray should not be used after the date marked "EXP" on the pack.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

Clear, colourless solution.

- Ingredients

- Active ingredient  
200 I.U. synthetic salmon calcitonin per metered dose.
- Inactive ingredients:  
Benzalkonium chloride, sodium chloride, hydrochloric acid (for pH adjustment), purified water.

- MAL Number

MAL19990991ACRZ

**Manufacturer:**

Delpharm Huningue S.A.S.,  
Huningue, France for Novartis Pharma AG, Basle, Switzerland.

**Product Registration Holder**

Novartis Corporation (Malaysia) Sdn. Bhd.  
Level 22, Tower B, Plaza 33,  
No. 1, Jalan Kemajuan, Seksyen 13,  
46200 Petaling Jaya  
Selangor Darul Ehsan, Malaysia

**Date of revision**

11/03/2016

**Serial Number:**

BPFK(R4/1)090316/00072

## INFORMATION FOR CONSUMERS

### When and how to use Miacalcic Nasal Spray

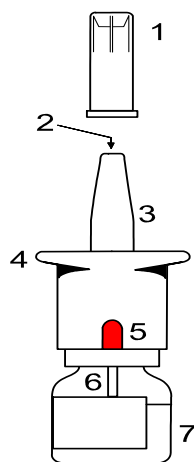
This medicine is for administration into the nostrils only. You should switch between each nostril every time you use Miacalcic Nasal Spray. Your pharmacist has stored Miacalcic Nasal Spray in a refrigerator. Before you start using it, you should let the spray reach room temperature.

### Instructions for use/handling of Miacalcic Nasal Spray

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


- The different parts of the nasal spray.
- How to prepare a new nasal spray for use.
- Using the nasal spray.
- If the spray mechanism should become blocked, this may be resolved by pressing down firmly on the pump; do not attempt to unblock it by using a sharp pointed object as this may cause damage. If you think your nasal spray is not working properly, take it back to your pharmacist. Never try to fix the nasal spray yourself or take it apart, as this may affect your dose.
- Always follow your doctor's instructions regarding dosage carefully.
- Keep this leaflet in a safe place so that you can read it again.

### The different parts of your nasal spray




1. **Protective cap:** Keeps the nozzle clean and protects the jet. Always

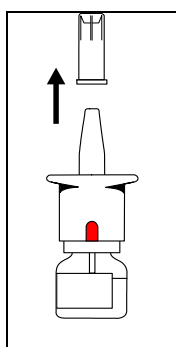
replace the protective cap after you have used the nasal spray.

2. **Jet:** The tiny hole from which the solution 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 this picture. The display will change as you use the pump (see below).
6. **Dip tube:** The tube inside the spray bottle that draws up the solution when you press the pump.
7. **Bottle:** Contains enough solution for at least 14 doses.

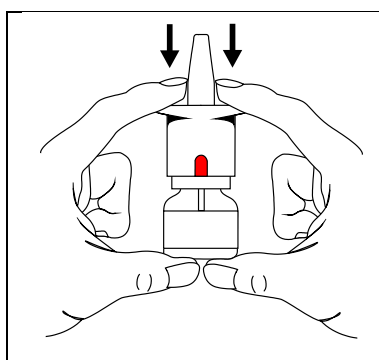
### Preparing a new nasal spray bottle for use

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

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



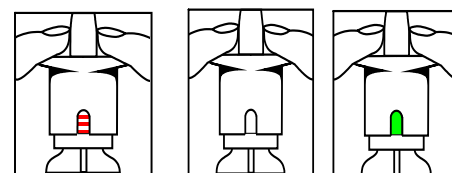
- First, remove the protective cap.







- 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 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 solution sprays out; this is normal.



- As you press the pump, watch the changes in the dose counter window.  
 to  to  to 
- When green is showing in the dose counter window, your new nasal spray is ready to use.
- Follow the instructions for 'Using your nasal spray'.

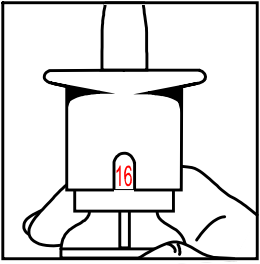
### Using your nasal spray



- With the protective cap removed, 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 once only.
- Remove the nasal spray from your nose and breathe in deeply through your nostril to help keep the solution 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.

### 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 extra doses.



When the dose counter window shows a red 16 as shown in this picture, 16 puffs have been used and the nasal spray is finished. You may notice that a little liquid is left in the nasal spray bottle, but this is normal.

If you are not sure how to use your spray bottle, ask your doctor or pharmacist.