

**Miacalcic® 50 IU/1 ml,
Miacalcic® 100 IU/1 ml,
Miacalcic® 400 IU/2 ml Solution for Injection and Infusion**
Calcitonin (salmon, synthetic)

Patient Information Leaflet

This medicine will usually be referred to just as Miacalcic in this leaflet.

Read all of this leaflet carefully before you start treatment with this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Miacalcic is and what it is used for
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1. WHAT MIACALCIC IS AND WHAT IT IS USED FOR

Miacalcic 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 can be given for the following conditions:

- Prevention of bone loss in patients who have suddenly become immobile. For example patients who have osteoporosis (thin and weak bones) and are bed-bound because of a fracture.
- Paget's disease of bone: A slowly progressing illness which can cause a change in the size and shape of certain bones.
- Treatment of high levels of calcium in the blood (hypercalcemia) due to cancer.

2. BEFORE YOU TAKE MIACALCIC

Do not take Miacalcic

- if you are allergic (hypersensitive) to calcitonin (salmon, synthetic) or any of the other ingredients of Miacalcic;
- if you have a very low calcium level in your blood (hypocalcaemia).

Take special care with Miacalcic

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is particularly important to tell your doctor if you are taking medicines:

- used to treat **heart problems** (e.g. digoxin) or **high blood pressure** (e.g. amlodipine, diltiazem);
- containing **lithium**, as the dose of lithium may need to be changed;
- containing **bisphosphonate** (used to treat osteoporosis).

Children and adolescents (age under 18 years)

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

Older people

Miacalcic can be used by older people without any specific requirements.

Pregnancy and breast-feeding

Miacalcic should **not** be used by pregnant and breast-feeding women.

If you are, or think you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Miacalcic

The solution contained in Miacalcic ampoules contains less than 23 mg sodium per 1 ml and can therefore be considered as sodium-free.

3. HOW TO TAKE MIACALCIC

Always take Miacalcic exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. It is advisable to administer the medication at bedtime in order to reduce the occurrence of nausea (feeling sick) or vomiting (being sick) which may occur especially at the beginning of the therapy.

Do not exceed the recommended dosage. Do not take Miacalcic if you notice that the solution is not clear and colourless. Do not change the dose or stop treatment without first talking to your doctor.

Miacalcic is usually given by injection either into the tissue just under the skin (subcutaneous injection) or into a muscle (intramuscular injection). Occasionally, the injection is given by a slow infusion into a vein (slow intravenous infusion).

If you will be giving yourself subcutaneous injections, make sure you understand exactly how to prepare and give them. Your doctor or nurse will give you precise instructions. Do not inject yourself unless you are confident of your ability to do so.

You should not use the injection or infusion straight from the fridge. Let it reach room temperature naturally first. The ampoules should be used immediately after opening. Excess amount of Miacalcic should be discharged.

The dosage to be used depends on your condition and response to the medicine. Your doctor will tell you exactly how much Miacalcic you should take.

The usual doses are:

- **For prevention of bone loss:** 100 IU per day or 50 IU twice daily for 2 to 4 weeks, given into the muscle or the tissue just under the skin.
- **For Paget's disease:** 100 IU daily injected into a muscle or into the tissue just under the skin.
- **For the treatment of high calcium levels:** 100 IU every 6 to 8 hours, given into a muscle or into the tissue just under the skin. In some cases, it may be given by injection into a vein.

If you inject more Miacalcic than you should

If you accidentally inject too much Miacalcic, contact your **doctor immediately**. You may require medical attention.

If you forget to inject Miacalcic

If you forget to inject yourself a dose, give it as soon as you remember it unless it is less than 4 hours until your next dose is due. In that case, wait and inject your next dose at the usual time. Do not inject a double dose to make up for a forgotten one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Miacalcic can cause side effects, although not everybody gets them. The most frequently observed side effects are nausea, vomiting and redness of the face/neck.

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 (affecting more than 1 in 10 patients):

- Feeling sick with or without being sick. These are less frequent when the injection is done in the evening and after meals.
- Sudden waves of redness of the face and/or neck, usually observed 10 to 20 minutes after injection.

Common side effects (affecting less than 1 in 10 patients):

- diarrhoea, stomach pain,
- tiredness,
- pain in bone, joints or muscles
- dizziness,
- headache,
- changes in the way things taste

Uncommon side effects (affecting less than 1 in 100 patients):

- high blood pressure (hypertension),
- flu-like symptoms,

- redness and swelling at the injection site, skin rash, itching
- disturbed vision
- frequent need to pass water,
- allergic reactions

Rare side effects (affecting less than 1 in 1,000 patients):

Calcium levels in your blood can fall 4 to 6 hours after dose administration, it is unlikely that you notice any symptoms because of this.

In rare cases, the effectiveness of Miacalcic may be reduced.

If any of the side effects gets severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MIACALCIC

Keep out of the reach and sight of children.

Do not use Miacalcic after the expiry date which is stated on the label after “exp”. The expiry date refers to the last day of that month.

The unopened ampoules and vials should be stored in a refrigerator (2-8°C). Do not freeze. The ampoules should be used immediately after opening. If you do not use the whole of the ampoule, DO NOT keep the remainder.

Once the vial has been opened it can be kept at room temperature (not above 25°C) for up to one month. If there is anything left afterwards throw it away.

For infusion, use Miacalcic immediately after dilution in 0.9% w/v sodium chloride in soft PVC bags.

Do not take Miacalcic if you notice that the solution is not clear and colourless.

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.

6. FURTHER INFORMATION

What Miacalcic contains

Miacalcic is available in three different strengths.

It comes in ampoules containing 1 ml of solution containing either 50 or 100 IU of the active ingredient, calcitonin (salmon, synthetic). These are for single use only. The solution also contains acetic acid, sodium acetate trihydrate, sodium chloride and water for injections.

It also comes as a vial containing 2 ml of solution containing 400 IU of calcitonin (salmon, synthetic). The vials can be used more than once. The solution also contains acetic acid, sodium acetate trihydrate, sodium chloride, water for injections and the preservative, phenol.

One IU (International Unit) corresponds to 0.167 micrograms calcitonin (salmon, synthetic).

What Miacalcic looks like and contents of the pack

Miacalcic is a solution for injection and infusion.

Miacalcic ampoules are made of uncoloured glass that contain 1 ml of clear, colourless solution for injection and infusion.

Packs of 5, 10, 50 and 100 ampoules are registered. Some of these may not be available.

Miacalcic vials are made of clear glass and contain 2 ml of clear, colourless solution for injection and infusion.

Each Miacalcic pack contains one vial.

The product licence holder is

Novartis Pharmaceuticals UK Ltd

Trading as Sandoz Pharmaceuticals, Frimley Business Park, Frimley, Camberley, Surrey
GU16 7SR, England.

The manufacturer responsible for release on to the market is

Novartis Pharmaceuticals UK Ltd

Wimblehurst Road, Horsham, West Sussex RH12 5AB, England.

This leaflet was approved in July 2009.

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.

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