

PACKAGE LEAFLET

Package leaflet: Information for the user

Miacalcic 50 IU/ml solution for injection and infusion

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

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 are bed-bound because of a fracture.
- Paget's disease of bone in patients who cannot take other treatments for this condition, for example patients with serious kidney problems. Paget's disease is a slowly progressing illness which can cause a change in the size and shape of certain bones.
- Treatment of high calcium levels in the blood (hypercalcemia) due to cancer.

2. What you need to know before you take Miacalcic

Do not take Miacalcic

- 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 (hypocalcemia).

Warning and precautions

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

Please tell your doctor if you have been diagnosed with cancer. In clinical trials, patients treated with calcitonin for osteoporosis and osteoarthritis have shown an increase in the risk of cancer following long term treatment. Your doctor will decide if calcitonin is a suitable treatment for you and for how long you can be treated.

Children and adolescent (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.

Other medicines and Miacalcic

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 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).

Pregnancy and breast-feeding

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

Miacalcic contains sodium

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

3. How to take Miacalcic

Always take this medicine exactly as your doctor has told you. 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.

Your doctor will decide the correct dose and how long you should receive calcitonin treatment depending on your condition.

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, normally for up to 3 months. In some cases, your doctor might decide to extend your treatment up to 6 months.
- **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 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 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 (may affect more than 1 in 10 people):

- 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 (may affect up to 1 in 10 people):

- diarrhoea, stomach pain,
- tiredness,
- pain in bone or joints,
- pain in muscles,
- dizziness,
- headache,
- changes in the way things taste,
- cancer (following long term treatment)

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

- 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 (may affect up to 1 in 1,000 people):

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.

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

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2-8°C). Do not freeze.

The ampoules should be used immediately after opening.

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

Do not take this medicine if you notice that the solution is not clear and colorless.

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 contains

- The active substance is calcitonin (salmon, synthetic). Each 1 ml of Miacalcic solution for injection and infusion contains 50 IU. One IU (International Unit) corresponds to 0.167 micrograms calcitonin (salmon, synthetic).
- The other ingredients are acetic acid, sodium acetate trihydrate, sodium chloride and water for injection.

What Miacalcic looks like and contents of the pack

Miacalcic 50 IU/ml 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.

Miacalcic 50 IU/ml solution for injection and infusion is available in packs of 5, 10, 50 and 100 ampoules.

Miacalcic is also available as 100 IU/ml solution for injection and infusion.

Not all strengths and pack sizes may be available in your country.

Marketing Authorisation Holder

Essential Pharma Ltd
7 Egham Business Village
Crabtree Road
Egham
Surrey TW20 8RB
United Kingdom

Manufacturer

Novartis Pharmaceuticals UK Limited
Frimley Business Park
Frimley
Camberley
Surrey GU 16 7SR
England

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

Austria	Calcitonin Essential Pharma
Belgium	Miacalcic
France	Miacalcic
Ireland	Miacalcic
Italy	Calcitonina Essential Pharma
United Kingdom	Calcitonin

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