

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Miacalcic.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page.

Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Miacalcic against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Miacalcic is used for

Miacalcic contains calcitonin salmon (salcatonin), which is similar to calcitonin, a hormone produced by the body.

- Miacalcic is used to treat Paget's disease when other therapies cannot be used or have proven unsuccessful

Paget's disease is a chronic disorder of the bones of the skeleton. Bone is a living tissue and, just like other parts of the body, it is constantly being renewed. This process is called bone remodelling.

Remodelling involves two types of bone cells - osteoclasts, which break down old bone and osteoblasts, which make new bone. In people with Paget's disease the osteoclasts in some bones are overactive, causing the bone to break down more quickly than usual. The osteoblasts then try to work faster to replace the lost bone. The new bone that is formed may be thicker but weaker than normal, which can cause pain and may lead to fractures (broken bones).

Miacalcic works by slowing down the breakdown of bone by the osteoclasts. This allows bone remodelling to go back to normal and protects the bones from being weakened. Miacalcic may also relieve bone pain.

- Miacalcic is also used to treat hypercalcaemia (high calcium levels in the blood)

It helps to reduce the level of calcium in the blood when it becomes too high.

Ask your doctor if you have any questions about why Miacalcic has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Miacalcic is only available with a doctor's prescription. It is not addictive.

Miacalcic is not recommended for children except in special cases, since experience with using Miacalcic in this age group is limited.

Before you use Miacalcic

When you must not use it

Do not use Miacalcic if you have an allergy to:

- calcitonin salmon (salcatonin), the active ingredient in Miacalcic
- any of the other ingredients listed at the end of this leaflet

You may get hives or an itchy skin rash, swelling of the face, lips, tongue or throat, wheezing or troubled breathing, fast heart beat, faintness or other symptoms if you use it.

Your doctor may have performed a skin test to check for an allergy before giving you this medicine. See the 'Side Effects' section of this leaflet for more information about allergic reactions.

Do not use Miacalcic if you are pregnant or breast-feeding.

There is not enough experience with Miacalcic in pregnant women or nursing mothers to recommend its use. Your doctor can discuss with you the risks and benefits of using this medicine while you are pregnant or breast-feeding.

Do not use Miacalcic if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Do not use Miacalcic after the use by (expiry) date printed on the pack or ampoule.

If you use it after the expiry date has passed, it may not work as well as it should.

Before you start to use it

Tell your doctor if you have any problems with your kidneys.

Your doctor may want to prescribe a lower dose of Miacalcic than usual if you have a kidney problem.

Taking other medicines

Tell your doctor if you are taking lithium. Your dosage may need to be adjusted.

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Other medicines may affect the way Miacalcic works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell him/her before you use Miacalcic.

How to use Miacalcic

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How it is given

Miacalcic cannot be taken by mouth because it is rapidly broken down in the stomach. Instead it is given as an injection. It can be injected intravenously (into the vein) or intramuscularly (into the muscle of the thigh

or buttock). It can also be injected subcutaneously. That means that it is injected into the layer of fat just under the skin.

If you will be giving the subcutaneous injections yourself, your doctor or nurse will teach you how to inject yourself properly.

If you are not sure about anything, ask your doctor or nurse before you start.

How much is given

The dose of Miacalcic depends on the condition being treated.

For Paget's disease: the usual dose is 80 to 100 I.U. (international units) of Miacalcic each day or every second day. The dose is given by intramuscular or subcutaneous injection. The dose of Miacalcic may be adjusted depending on the response to treatment. This medicine may be needed for anywhere from a few months to a few years.

For hypercalcaemia: the usual dose is 5 to 10 I.U. of Miacalcic per kg of body weight per day. It can be given intravenously or by intramuscular or subcutaneous injection.

If you forget to use it

If it is more than 4 hours until your next dose is due, inject the dose as soon as you remember and then go back to injecting it as you would normally.

If it is less than 4 hours until your next dose is due, wait and inject your dose at the usual time.

Do not use a double dose to make up for the one that you missed.

It won't do any harm if you miss a dose but some of your symptoms may come back temporarily until you get back on schedule.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that an overdose has happened. Do this even if there are no signs of discomfort or poisoning.

While you are using Miacalcic

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

If you have to take Miacalcic for a long time (for example, to treat Paget's disease), your doctor may want you to have X-rays or blood and urine tests from time to time to make sure Miacalcic is working and to prevent unwanted side effects from happening. If you are receiving Miacalcic solution for injection or infusion for a long time, tell your doctor and your doctor would evaluate the benefit against possible risks and advise you. Using Miacalcic for a long time might increase the risk of cancer.

See your doctor if your symptoms reappear.

Sometimes after using Miacalcic for a while, your symptoms may reappear (this is called a "rebound" effect). If this happens, your doctor may stop Miacalcic for a short time

and then start it again. This helps to restore the good effects of the medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having treatment with Miacalcic.

Tell any other doctor, dentist or pharmacist who treats you that you are having treatment with Miacalcic.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use Miacalcic to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Miacalcic affects you.

This medicine may cause dizziness in some people. Make sure you know how you react to Miacalcic before you drive a car, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Miacalcic.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- redness, swelling or pain at the site of injection
- nausea or vomiting
- abdominal pain
- a hot flushed face
- dizziness
- frequent passing of urine or passing large amounts of urine
- diarrhoea
- headache
- fever and chills
- pain in the joints
- numbness, tingling or cramps in arms or legs
- itching of the palms of the hands
- unusual taste
- fatigue
- visual disturbances
- trembling

Stop using Miacalcic and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- a severe reaction at the site of injection
- swelling of the face, lips, tongue or throat
- swelling of other parts of the body such as legs or ankles
- tightness in the chest, wheezing or troubled breathing
- hives or an itchy skin rash (can affect entire body)

- fast heartbeat
- fainting

You may be having a serious allergic reaction to Miacalcic and may need urgent medical attention or hospitalisation. Allergic reactions are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Miacalcic

Storage

- Keep the ampoules in the carton until it is time to use them.
- Keep your ampoules in the refrigerator (about 2°C to 8°C). Do not freeze.

Keep the medicine where children cannot reach it.

Disposal

Throw out any Miacalcic left in the ampoule once the dose has been injected.

Miacalcic does not contain any preservatives.

Dispose of the used ampoules safely.

If your doctor tells you to stop using Miacalcic or you find that it has passed the expiry date or has been left out of the fridge, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Each Miacalcic pack contains 5 ampoules of calcitonin salmon (salcatonin).

Ingredients

Each 1 mL ampoule of Miacalcic contains either 50 I.U. or 100 I.U. calcitonin salmon (salcatonin). The ampoule also contains glacial acetic acid, sodium acetate, sodium chloride and water for injections.

Sponsor

Miacalcic is supplied in Australia by:

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street,
Hawthorn East, VIC. 3123
Australia
E: medicalaffairs.au@chiesi.com
W: www.chiesi.com.au

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Australian Registration Number:

50 I.U./1 mL ampoule: AUST R 13364

100 I.U./1 mL ampoule: AUST R 13363