

MIACALCIC

Calcitonin salmon (salcatonin)

100 IU/1mL solution for injection

What is in this leaflet

Please read this leaflet carefully before you start using MIACALCIC.

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.

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 acute bone pain when bone deteriorates after hip repair or surgery, or spinal compression fractures.
- 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.

- Together with physiotherapy, MIACALCIC is also used to treat neurodystrophic disorders (local bone destruction due to dysfunction of the nerves) when other therapies cannot be used or are unsuccessful
- as accompanying treatment of pancreatitis (inflammation of the pancreas).

Your doctor may have prescribed MIACALCIC for another reason.

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

This medicine is available only with a doctor's prescription.

MIACALCIC is not considered habit forming.

Before you use MIACALCIC

When you must not use it

Do not use MIACALCIC if you have an allergy to:

- 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 heartbeat, 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.

If you are not sure whether you should start using MIACALCIC, talk to your doctor.

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

If you have not told your doctor about any of the above, tell them before you start using MIACALCIC.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking MIACALCIC.

Some medicines may interfere with MIACALCIC. These include:

- lithium

This medicine may be affected by MIACALCIC, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MIACALCIC.

How to use MIACALCIC

How much to take

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.

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.

The dose of MIACALCIC depends on the condition being treated and your body's response to the medicine. Your doctor will tell you exactly how much MIACALCIC you need and for how long.

Do not use more than advised by your doctor. You should not use it for longer than advised by your doctor.

For Paget's disease: the usual dose is 100 IU (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 acute bone pain: the usual dose is 100 to 200 IU of MIACALCIC each day, given by slow intravenous infusion in saline, or by subcutaneous or intramuscular injection for up to four weeks. It may take several days to relieve the pain.

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

For neurodystrophic disorders: the usual dose is 100 IU daily by subcutaneous or intramuscular injection for 2 – 4 weeks. A dose of 100 IU may be given every second day for up to 6 weeks after that period depending on your progress. Your doctor will determine how long treatment should be continued.

Acute pancreatitis: 300 IU by intravenous infusion in normal saline over a 24-hour period for up to 6 consecutive days.

When to take it

Your doctor will tell you exactly when to take MIACALCIC you need and for how long.

Do not use more than advised by your doctor. You should not use it for longer than advised by your doctor.

How long to take it

Your doctor will tell you exactly how much MIACALCIC you need and for how long. You should not use it for longer than advised by your doctor.

Do not stop taking this medicine unless your doctor tells you to. If you stop taking the capsules your condition may get worse.

If you forget to take 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.

MIACALCIC is only intended for the use of the consumer it has been prescribed for.

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.

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 taking 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 MIACALCIC to anyone else, even if they have the same condition as you.

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

Do not stop taking this medicine unless your doctor tells you to. If you stop taking the capsules your condition may get worse.

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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MIACALCIC.

Do this even if there are no signs of discomfort or poisoning.

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, most of the time they are not. You may need medical treatment if you get some of the adverse 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 or neck
- dizziness
- frequent passing of urine or passing large amounts of urine
- diarrhoea
- headache
- fever and chills, sore throat (flu-like symptoms)
- pain in bones and joints
- pain in muscles
- numbness, tingling or cramps in arms or legs
- itching of the palms of the hands
- unusual taste
- abdominal pain
- tiredness
- disturbed vision
- high blood pressure
- 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
- fast heartbeat
- fainting due to a fall in blood pressure

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.

In clinical studies where calcitonin was used for a long time, a small increased risk for cancer was observed.

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

After using MIACALCIC

Storage

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 carton and ampoule. The expiry date refers to the last day of that month.

- 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.

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 salcatonin.

Ingredients

Active ingredient:

Each 1 mL ampoule of MIACALCIC contains 100 IU salcatonin (also known as calcitonin salmon).

Inactive ingredients:

The ampoule also contains:

- glacial acetic acid
- sodium acetate
- sodium chloride
- water for injections

Sponsor Details

Chiesi New Zealand Ltd
Bellingham Wallace Ltd
Suite 1, 470 Parnell Road
Parnell
Auckland 1052

Distributed in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Mangere
Auckland 2022

Email: medicalaffairs.au@chiesi.com

Website: www.chiesi.com.au

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