

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MIACALCIC?

MIACALCIC contains the active ingredient calcitonin salmon. MIACALCIC is used to treat Paget's disease (a bone disorder) when other treatments have not worked or can't be used. It is also used to help to reduce the level of calcium in the blood when it becomes too high (hypercalcaemia). For more information, see Section [1. Why am I using MIACALCIC?](#) in the full CMI.

2. What should I know before I use MIACALCIC?

Do not use if you have ever had an allergic reaction to MIACALCIC or any of the ingredients listed at the end of the CMI.

Do not use MIACALCIC if you are pregnant or breastfeeding.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I use MIACALCIC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MIACALCIC and affect how it works. A list of these medicines is in [Section 3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MIACALCIC?

- Your doctor will decide the dose and provide you with instructions on how MIACALCIC should be used.
- For Paget's disease the usual dose is 80 to 100 I.U. (International Units) of MIACALCIC each day or every second day, given by intramuscular, or subcutaneous injection which you may give yourself.
- For hypercalcaemia the usual dose is 5 to 10 I.U. of MIACALCIC per kg of body weight per day, given intravenously or by intramuscular injection by the doctor or nurse, or subcutaneous injection which you may give yourself.

More instructions can be found in Section [4. How do I use MIACALCIC?](#) in the full CMI.

5. What should I know while using MIACALCIC?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you become pregnant.• Tell your doctor if you have any problems with your kidneys.• Tell your doctor if you are taking lithium.• See your doctor if your symptoms come back ("rebound" effect).• Remind any doctor, dentist or pharmacist you visit that you are using MIACALCIC.
Things you should not do	<ul style="list-style-type: none">• Do not dilute MIACALCIC when having it for intramuscular or subcutaneous injection.• For an intravenous infusion (which must be diluted), MIACALCIC must not be diluted in anything other than 0.9% sodium chloride solution.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how MIACALCIC affects you, because it may cause dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep your ampoules in the original carton in the refrigerator (between 2°C and 8°C, do not freeze), until it is time to use them.

For more information, see Section [5. What should I know while using MIACALCIC?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include feeling sick, diarrhoea, stomach pain, dizziness, headache, changes in taste, feeling tired, pain in your joints. The serious side effects that you need urgent attention for include serious reaction at the injection site and sudden allergic reaction (skin rash or hives, problems breathing, swollen face and/or body, fast heartbeat, fainting).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MIACALCIC®

Active ingredient: *calcitonin salmon*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MIACALCIC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MIACALCIC.**

Where to find information in this leaflet:

- [1. Why am I using MIACALCIC?](#)
- [2. What should I know before I use MIACALCIC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MIACALCIC?](#)
- [5. What should I know while using MIACALCIC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MIACALCIC?

MIACALCIC contains the active ingredient **calcitonin salmon**. It is similar to calcitonin, a hormone produced by your body.

MIACALCIC is used to treat Paget's disease when other treatments have not worked or can't be used. Paget's disease is a long-term disorder of the bones. MIACALCIC protects the bones from being weakened and may also relieve bone pain.

MIACALCIC is also used to treat hypercalcaemia (high calcium level in the blood). It helps to reduce the level of calcium in the blood when it becomes too high.

2. What should I know before I use MIACALCIC?

Warnings

Do not use MIACALCIC if:

- you are pregnant or breastfeeding
- you are allergic to calcitonin salmon, or any of the ingredients listed at the end of this leaflet. Your doctor may have performed a skin test to check for an allergy before giving you this medicine. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, especially kidney problems. Your doctor may want to prescribe a lower dose of MIACALCIC than usual if you have a kidney problem
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use MIACALCIC if you are pregnant.

Talk to your doctor if you are pregnant or intend to become pregnant.

Do not use MIACALCIC if you are breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is not enough experience with MIACALCIC in pregnant women or nursing mothers to recommend its use.

Children and adolescents

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

What if I am taking other medicines?

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

Some medicines may interfere with MIACALCIC and affect how it works. This includes:

- Lithium (a medicine used to mental illness). Your dosage may need to be adjusted.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MIACALCIC.

3. How do I use MIACALCIC?

How much to use

The dose of MIACALCIC depends on your medical condition.

- 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 how your body responds to it.
 - You may need to have it anywhere from a short time 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.
- Follow the instructions provided by your doctor and use MIACALCIC until your doctor tells you to stop.

When to use MIACALCIC

For Paget's disease MIACALCIC should be used daily or every second day.

For hypercalcaemia: MIACALCIC should be used every day.

How to use MIACALCIC

MIACALCIC is given as an injection. It can be injected intravenously (into the vein) or intramuscularly (into the muscle of the thigh or buttock). This will be done by a doctor or nurse.

It can also be injected subcutaneously (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 forget to use MIACALCIC

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

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

Do not have 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 too much MIACALCIC

If you think that you have had too much MIACALCIC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

4. What should I know while using MIACALCIC?

Things you should 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.

Using MIACALCIC for a long time might increase the risk of cancer. Your doctor will keep assessing the benefits against the possible risks of using this medicine.

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, you may need to stop MIACALCIC for a short time and then start it again. This helps to restore the good effects of the medicine.

Call your doctor straight away if you:

- become pregnant while taking this medicine
- feel sick or have other digestive problems. These may be short-lived problems and your doctor may give you another medicine to help with these or change the dose of MIACALCIC or how often it is given.
- have a serious reaction at the site of the injection.
- have an allergic reaction that affects other parts of your body

Remind any doctor, dentist or pharmacist you visit that you are using MIACALCIC.

Things you should not do

- Do not dilute MIACALCIC when having it for intramuscular or subcutaneous injection.
- When having it as an intravenous infusion (which must be diluted), MIACALCIC must not be diluted in anything other than 0.9% sodium chloride solution.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MIACALCIC affects you.

MIACALCIC 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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Keep it where young children cannot reach it.

When to discard your medicine

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

MIACALCIC does not contain any preservatives.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, or has been left out of the fridge, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

5. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Blood and urine tests</p> <ul style="list-style-type: none"> too little calcium in the blood <p>Circulation</p> <ul style="list-style-type: none"> a hot flushed face high blood pressure <p>Digestive system</p> <ul style="list-style-type: none"> abdominal pain diarrhoea feeling or being sick <p>Eyes</p> <ul style="list-style-type: none"> problems seeing properly <p>General body</p> <ul style="list-style-type: none"> feeling tired or listless having a fever or chills or feeling of having the flu <p>Infusion/injection-related reaction</p> <ul style="list-style-type: none"> redness, swelling or pain at the site of injection <p>Muscles and bones</p> <ul style="list-style-type: none"> pain in the joints bone pain muscle spasms <p>Nervous system</p> <ul style="list-style-type: none"> dizziness headache unusual taste numbness, tingling or cramps in arms or legs trembling <p>Skin</p> <ul style="list-style-type: none"> itching skin skin rash <p>Urinary system</p> <ul style="list-style-type: none"> frequent passing of urine or passing large amounts of urine 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Infusion/injection-related reaction</p> <ul style="list-style-type: none"> a severe reaction (redness, swelling, pain) at the site of injection 	<p>Call your doctor straight away or go straight to the Emergency Department at</p>

<p>Hypersensitivity (allergic) reaction may include:</p> <ul style="list-style-type: none"> swelling of the face, lips, tongue or throat or other parts of the body such as legs or ankles tightness in the chest, wheezing or problems breathing hives (itchy raised bumps on the skin or an itchy skin rash (can affect entire body)) fast heartbeat fainting 	<p>your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

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

What MIACALCIC contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> calcitonin salmon
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> glacial acetic acid sodium acetate sodium chloride water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What MIACALCIC looks like

MIACALCIC is a clear, colourless solution that contains no particles. It comes in 1 mL clear glass ampoules.

Each carton contains 5 ampoules.

There are two strengths:

50 IU of calcitonin salmon in 1 mL

and

100 IU calcitonin salmon in 1 mL

Not all strengths may be marketed.

ARTG numbers:

MIACALCIC 50 IU/1 mL: AUST R 13364

MIACALCIC 100 IU/1 mL: AUST R 13363

Who distributes MIACALCIC

Chiesi Australia Pty Ltd

Level 7, Suite 1, 500 Bourke Street,

Melbourne, VIC 3000

Email: medinfo.au@chiesi.com

W: www.chiesi.com.au

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