

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 Aclasta?

Aclasta contains the active ingredient zoledronic acid. Aclasta is used to treat osteoporosis in postmenopausal women and in men, to prevent additional fractures in men or women who have recently had a hip fracture, or to treat or prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone. Aclasta is also used to treat Paget's disease of bone.

For more information, see Section [1. Why am I using Aclasta?](#) in the full CMI.

2. What should I know before I use Aclasta?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Aclasta 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 Aclasta?

- Aclasta will be given to you by infusion into a vein by your doctor or nurse once a year. The infusion will take at least 15 minutes.

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

5. What should I know while using Aclasta?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Aclasta.• If you get a headache, fever or other flu-like symptoms in the first three days after you are given Aclasta, take paracetamol if your doctor has told you to.• Take calcium and vitamin D supplements if your doctor has told you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Aclasta affects you.• If you are travelling home by car after the infusion, arrange to have someone else drive.
Looking after your medicine	<ul style="list-style-type: none">• It is unlikely you will have to store Aclasta at home.• Each Aclasta vial is to be used for one injection only and then discarded.

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

6. Are there any side effects?

Some of the common and serious side effects are included in the CMI. Speak to your doctor if you have side effects and they worry you.

Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin.

Tell your doctor and dentist immediately about any dental symptoms you get after you have Aclasta.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following after you have Aclasta: signs of a serious allergic reaction, signs that the level of calcium in your blood may have fallen too far, signs that the level of phosphorus in your blood may have fallen too far, and signs that your kidneys may not be working properly.

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.

ACLASTA®

Active ingredient(s): *zoledronic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aclasta. **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 Aclasta.**

Where to find information in this leaflet:

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

1. Why am I using Aclasta?

Aclasta contains the active ingredient zoledronic acid. Aclasta belongs to a group of medicines called bisphosphonates.

Aclasta is used to treat osteoporosis in postmenopausal women and in men, to prevent additional fractures in men or women who have recently had a hip fracture, or to treat or prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone.

Aclasta is also used to treat Paget's disease of bone.

Aclasta works by slowing down bone resorption, which allows the bone-forming cells time to rebuild normal bone. This allows bone remodelling to go back to normal and protects the bones from being weakened.

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

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children or adolescents.

2. What should I know before I use Aclasta?

Warnings

Do not use Aclasta if:

- you are allergic to zoledronic acid, or any of the ingredients listed at the end of this leaflet.** Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other bisphosphonate medicine such as alendronate or risedronate.** If you are not sure whether you are allergic to other

bisphosphonate medicines, talk to your doctor. Other bisphosphonate medicines have been shown to cause breathing difficulties in people with asthma who are allergic to aspirin.

- you have low levels of calcium in your blood.** Your doctor may do a blood test to check your calcium levels before you have Aclasta.
- the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have been or are being treated with:
 - Zometa® which contains the same active ingredient as in Aclasta
 - another bisphosphonate medicine prior to Aclasta
 - diuretic therapy (commonly called 'fluid tablets')
- have a kidney problem. This medicine is not suitable for some people with a kidney problem.
- have a calcium deficiency or a vitamin D deficiency
- are unable to take daily calcium or vitamin D supplements
- have had some or all of your parathyroid or thyroid glands in your neck surgically removed
- have had sections of your intestine removed
- have or have had pain, swelling or numbness of the jaw or loosening of a tooth or any other oral issues
- had or have joint stiffness, aches and pains and difficulty in movement (especially of the hip, thigh, knee or upper arm) or pain around the external ear canal
- are under dental treatment or will undergo dental surgery. Your doctor will check your oral health before you start treatment with Aclasta. It is important to have good dental hygiene, routine dental care and regular dental check-ups. Discuss with your doctor any planned dental surgery such as a tooth extraction. Tell your dentist that you are being treated with Aclasta.
- have or have had uveitis or iritis (inflammatory conditions of the eye).

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 have Aclasta if you are pregnant.

There is no information on use of this medicine in pregnancy.

Do not breast-feed while you are having treatment with Aclasta.

It is not known if the active ingredient, zoledronic acid, passes into the breast milk and could affect your baby.

3. 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 and Aclasta can interfere with each other. These include:

- medicines that may affect your kidneys such as fluid tablets
- aminoglycoside medicines used to treat severe infections.

You may need to take different amounts of these medicines or you may need to take different medicines. Your doctor or pharmacist has more information.

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

4. How do I use Aclasta?

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

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

If you do not understand the instructions, ask your doctor, nurse or pharmacist for help before treatment starts.

Make sure you drink enough fluids before and after the treatment with Aclasta as directed by your doctor.

Two glasses of fluid (such as water) before and after the infusion are usually enough. This will help to prevent dehydration.

You may eat normally on the day you are treated with Aclasta.

How it will be given

Aclasta will be given to you by infusion into a vein by your doctor or nurse once a year. The infusion will take at least 15 minutes.

How much is given

A 100 mL infusion will last at least 15 minutes.

How long treatment will last

- For osteoporosis, each dose of Aclasta lasts one year. Your doctor will check your condition and may prescribe further annual doses.
- For Paget's disease, each dose of Aclasta may work for longer than one year. Your doctor will let you know if you need to be treated again.

If you use too much Aclasta

If you think that you have been given too much Aclasta, 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.

Tell your doctor if you have any of the following symptoms:

- muscle spasms
- numbness or tingling sensation, especially around the mouth
- shortness of breath.

These symptoms may mean the level of calcium in your blood has fallen too far.

5. What should I know while using Aclasta?

Things you should do

If you get a headache, fever or other flu-like symptoms in the first three days after you are given Aclasta, take paracetamol if your doctor has told you to.

Some people get short-lasting flu-like symptoms after having Aclasta. Paracetamol can provide some relief.

Take calcium and vitamin D supplements if your doctor has told you to.

- Most people with osteoporosis do not get enough calcium and vitamin D in their diet and supplements are needed to help strengthen your bones.
- If you are being treated with Aclasta for Paget's disease, your doctor should advise corrective treatment for a vitamin D deficiency and that you take calcium and vitamin D supplements for at least the first ten days after you have Aclasta to reduce the risk of low calcium levels in your blood.

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

Your doctor may want you to have X-rays, bone density scans or blood tests from time to time to make sure Aclasta is working and to prevent unwanted side effects from happening.

Call your doctor and dentist straight away if you:

- **become pregnant while having treatment with this medicine.** Your doctor can discuss with you the risks of having it while you are pregnant.
- **experience any dental symptoms you get while you are being treated with Aclasta. This may include persistent pain, swelling, loosening of a tooth and/or non-healing sores or discharge (pus or oozing).** A dental condition called jaw osteonecrosis has been reported, primarily in patients being treated with this type of medicine for other illnesses.

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

Driving or using machines

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

Aclasta has no known effect on the ability to drive or use machines but, as a general precaution, if you are travelling home by car after the infusion, arrange to have someone else drive.

Looking after your medicine

- It is unlikely you will have to store Aclasta at home.

If you do have to store it:

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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the floor is a good place to store medicines.

Each Aclasta vial is to be used for one injection only and then discarded.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

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
<ul style="list-style-type: none"> short-lasting fever, sometimes with flu-like symptoms, headache, chills, pain or aching in the muscles or joints. Take paracetamol if your doctor has told you to. Paracetamol can provide some relief. redness, swelling or pain where the needle for the infusion was inserted upset stomach, abdominal pain, loss of appetite or other eating disorder, thirst or heartburn nausea, vomiting, diarrhoea, with possible dehydration 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> constipation dry mouth, toothache or sore throat lack of energy, tiredness and lack of interest, weakness, dizziness, low blood pressure pain in your back, neck, shoulders, arms, legs or chest muscles, swollen or stiff joints, muscle stiffness, weakness or spasm, tingling or numbness of your hands or feet swollen fingers or lower legs due to fluid build-up swollen, red, painful or itchy eyes or sensitivity of the eyes to light pink eye (conjunctivitis) palpitations (feeling of fast, forceful and/or irregular heartbeat), which may be accompanied by dizziness and breathlessness excessive sweating difficulty sleeping pain, weakness or discomfort in your thigh, hip or groin. Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur. Contact your doctor if you experience this as it may be an early sign of a possible fracture of the thigh bone 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> signs of allergy such as rash, itching or hives on the skin; swelling of the face, throat, lips, tongue or other part of the body; shortness of breath, difficulty breathing or swallowing; tightness of the chest signs that the level of calcium in your blood may have fallen too far, such as muscle spasms, numbness or tingling sensation, especially around the mouth, shortness of breath signs that the level of phosphorus in your blood may have fallen too far, such as muscle problems and weakness, confusion, irritation, and delirium 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • signs that your kidneys may not be working properly, such as decreased urine output • pain in the mouth, teeth and jaw, swelling of sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis). 	
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This leaflet was prepared in November 2025.

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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.

Some of these (e.g. effects on kidney function and on the level of calcium in the blood) can only be found by laboratory testing.

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.

7. Product details

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

What Aclasta contains

Active ingredient (main ingredient)	zoledronic acid
Other ingredients (inactive ingredients)	mannitol sodium citrate water for injections.

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

What Aclasta looks like

Aclasta – transparent plastic vial containing 100 mL of a clear, colourless solution. Aclasta is supplied as packs containing one vial (AUST R 134664).

Who distributes Aclasta

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369