

ACLASTA®

Zoledronic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aclasta.

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. 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. You can also download the most up-to-date leaflet from www.novartis.com.au.

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 having Aclasta against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Aclasta is used for

The active ingredient in Aclasta is zoledronic acid, which 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.

Osteoporosis is a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break. This is common in women after menopause, when a woman's ovaries stop producing the female hormone, oestrogen, which keeps bones healthy. It also occurs in men and women with increasing age. Broken bones may result from injury or simple falls. Breaks may occur during normal everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone. Fractures in people with osteoporosis usually occur at the hip, spine or wrist. These can lead not only to pain, but also to considerable deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

Paget's disease is a chronic disorder which may affect various 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. In Paget's disease, the bone material breaks down more quickly than usual, and new bone material grows more quickly than usual and in a disordered way. The new bone that is formed may be thicker but weaker than normal, which can

cause pain and may lead to fractures (broken bones).

How does it work

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.

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

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

Before you have Aclasta

When you must not have it

You must not have Aclasta if you have an allergy to:

- zoledronic acid (the active ingredient in Aclasta) or any of the other ingredients listed at the end of this leaflet
- any other bisphosphonate medicine such as alendronate (e.g. Fosamax) or risedronate (e.g. Actonel).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the

face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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.

Do not have Aclasta if 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.

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.

Do not have Aclasta after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist.

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

Before you have it

Tell 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')

Tell your doctor if:

- you have a kidney problem. This medicine is not suitable for some people with a kidney problem.
- you have a calcium deficiency or a vitamin D deficiency

- you are unable to take daily calcium or vitamin D supplements
- you have had some or all of your parathyroid or thyroid glands in your neck surgically removed
- you have had sections of your intestine removed
- you have or have had pain, swelling or numbness of the jaw or loosening of a tooth or any other oral issues
- you 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
- you 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.
- you have or have had uveitis or iritis (inflammatory conditions of the eye).

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including medicines 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.

How Aclasta is given

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 100mL 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 have 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.

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.

While you are being given Aclasta

Things you must 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.

Tell your doctor immediately 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.

Tell your doctor and dentist immediately about 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Aclasta.

Tell any other doctor, dentist or pharmacist who treats you that you are having Aclasta.

Things to be careful of

Be careful driving or operating machinery 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.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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
 - 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.
- Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early**

indication of a possible fracture of the thigh bone.

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur.

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

- 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).

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 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
- signs that your kidneys may not be working properly, such as decreased urine output.

The above side effects may be serious. You may need urgent medical attention.

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

Other side effects not listed above may also 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.

After having Aclasta

Storage

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

If you do have to store it:

- Store the medicine in a cool dry place at room temperature
- Do not store Aclasta or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep the medicine 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.

Disposal

If you no longer need Aclasta or it has passed its expiry date, return any unused medicine to your pharmacist.

Product description

What it looks like

Aclasta solution for infusion is supplied in a transparent plastic vial containing 100mL of a clear, colourless solution. Aclasta is supplied as packs containing one vial.

Ingredients

Each vial of Aclasta contains 5mg of zoledronic acid. Each vial also contains:

- mannitol

- sodium citrate
- water for injections.

Contains sodium and sulfites.

Sponsor

Aclasta is supplied in Australia by:
Novartis Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
Macquarie Park NSW 2113
Telephone 1-800-671-203
Web site: www.novartis.com.au

Date of preparation

This leaflet was prepared in April 2020.

AUST R 134664

® = Registered trademark

(ac1210420c.doc) based on PI (ac1210420i.doc)