

APO-Zoledronic Acid Solution for Infusion

Zoledronic acid monohydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about zoledronic acid 4mg/5mL. 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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may want to read it again.

What this medicine is used for

Zoledronic acid is used to lower the amount of calcium in the blood when it becomes too high, as may happen in some forms of cancer.

Some cancers can speed up normal changes in bone so that the amount of calcium released from the bones into the blood is increased.

Zoledronic acid is also used to slow down the spread of cancers in bone, helping to prevent changes to the bones that may cause them to weaken. It is used in people with advanced cancer of the bone marrow (called multiple myeloma) and other advanced cancers that have spread to

the bone. This medicine is used in addition to other standard cancer treatments.

How it works

Zoledronic acid belongs to a group of medicines called bisphosphonates, which strongly bind to bone. These medicines slow down the rate of bone change and help to restore the amount of calcium in the blood to normal.

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you use this medicine

When you must not use it

Do not use this medicine if you have an allergy to:

- zoledronic acid
- any other bisphosphonates such as alendronate or risedronate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- cough, shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Do not take this medicine if you are pregnant or plan to become pregnant.

Zoledronic acid may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

Zoledronic acid may pass into human breast milk and affect the baby.

Do not take this medicine 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 for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver problems
- heart conditions

- asthma and you are allergic to aspirin
- surgery on your thyroid
- pain in the teeth, gums or jaw, swelling or numbness of the jaw or a 'heavy jaw feeling' or loosening of a tooth.

Tell your doctor if you have been treated with or are being treated with:

- other medicines which contain zoledronic acid
- other bisphosphonate medicines
- diuretic therapy (commonly called 'fluid tablet')

Tell your doctor if you are receiving or are planning to receive dental treatment.

A dental condition called jaw osteonecrosis has been reported in some patients being treated with zoledronic acid or other drugs in the same class as zoledronic acid. It is advisable to have a dental check-up before starting zoledronic acid. You may need to have dental treatment completed before starting this medicine. Tell your dentist you may be receiving zoledronic acid.

Tell your doctor if you are planning to have surgery or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and zoledronic acid may interfere with each other. These include:

- medicines that may affect your kidneys, such as fluid tablets
- aminoglycoside medicines, used to treat severe infections. This combination may cause the level of calcium in the blood to become too low
- anti-angiogenic medicines as part of your cancer treatment, which

may increase the risk of bone damage in the jaw (osteonecrosis)

- any other medicine containing zoledronic acid, or other bisphosphonates such as risedronate, alendronate
- thalidomide, used to treat multiple myeloma
- loop diuretics, used to treat high blood pressure or oedema.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with zoledronic acid.

How this medicine is given

Zoledronic acid is given over at least 20 minutes via infusion into a vein. You may also be given an infusion of fluids to ensure that you do not become dehydrated.

You will have a blood test before each dose of zoledronic acid to make sure the medicine is not affecting your kidneys.

How much you will be given

Your doctor will tell you how much of this medicine you will be given. This will depend on your condition and whether you are taking any other medicines. Your doctor may give you a lower dose if you have a mild kidney problem.

To lower the amount of calcium in the blood, the usual dose of zoledronic acid is 4 mg, given as a single infusion.

To treat cancer in the bone, the usual dose is 4 mg, given as an infusion every 3 to 4 weeks.

Your doctor may also prescribe a daily calcium supplement and a multivitamin containing Vitamin D.

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

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have had too much of this medicine.

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

You may need urgent medical attention.

Symptoms of an overdose may include:

- unusual light headedness, dizziness or faintness
- numbness or tingling sensation
- muscle cramps.

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

While you are being given this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you have any dental symptoms, including pain or

unusual feeling in your teeth of gums, or any dental infections.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

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

If you are returning home immediately after the infusion, arrange to have someone else drive.

Practice good dental hygiene. Your routine dental hygiene should include:

- brushing your teeth and tongue after every meal and at bedtime
- gentle flossing once a day to remove plaque
- keeping your mouth moist by drinking water (many cancer medicines can cause 'dry mouth' which can lead to decay and other dental problems)
- avoiding use of mouthwash that contains alcohol

Use a mirror to check your teeth and gums regularly for any changes such as sores or bleeding gums. If you notice any problems, tell your doctor and dentist immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking zoledronic acid.

This medicine helps most people, but it may have unwanted side effects in a few people. 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 lists 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:

- redness, swelling or pain where the needle for the infusion was inserted
- stomach complaints, such as upset stomach, abdominal pain, loss of appetite, nausea (feeling sick) or vomiting, constipation or diarrhoea
- increased weight
- dry or sore mouth
- anxiety, confusion, difficulty sleeping
- headache, facial pain
- changes in taste sensation
- cough
- increased sweating

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- irritated eyes, blurred vision, eye pain, sensitivity to light, runny, itchy or swollen eyes
- tingling or numbness of the hands or feet
- swollen aching joints or muscles, pain in the bones
- slow or irregular heartbeat
- swelling of fingers or lower legs due to fluid build up
- short-lasting fever, sometimes with flu-like symptoms: such as chills; tiredness; fatigue; weakness; aches and pains, and joint pain and swelling
- passing less urine than normal, blood in the urine

The above list includes serious side effects that may require medical attention.

If any of the following happen, the infusion must be stopped, and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty breathing with wheezing or coughing

- signs that the level of calcium in your blood may have fallen too far, such as unusual light headedness, dizziness or faintness, numbness or tingling sensation, muscle cramps, convulsions or spasms.
- constant "flu-like" symptoms (chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy) that could be a sign of blood problems
- chest pain
- seizures
- pain in the mouth, teeth or jaw, swelling or sores inside the mouth, numbness or a "heavy jaw feeling" or loosening of a tooth. These symptoms could be a sign of a jaw-bone problem known as jaw osteonecrosis
- cough, 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; fainting; hayfever-like symptoms (signs of an allergic reaction)
- pain, weakness or discomfort in your thigh, hip or groin, as this may be an early sign of a possible fracture of the thigh bone. Patients taking zoledronic acid may be at risk of unusual fracture of the thigh bone.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

It is unlikely that you will have to store zoledronic acid at home.

If you have to store it:

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of the vial it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

in 5 mL, or 100 mL of solution, as the active ingredient.

It also contains the following:

- mannitol
- sodium citrate
- water for injections

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia

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Product description

What APO-Zoledronic Acid 4mg/5mL looks like

This medicine is packaged in plastic vials containing a clear, colourless, sterile solution.

AUST R 190337

Packs of 1, 4 or 10 vials

* Not all strengths, pack types and/or pack sizes may be available.

What APO-Zoledronic Acid 4 mg/100 mL looks like

This medicine is packaged in glass vials containing a clear, colourless, sterile solution.

AUST R 205927

Packs of 1, 4 or 5 vials

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each vial contains 4.264 mg of zoledronic acid (as monohydrate), equivalent to 4 mg of zoledronic acid