

## APO-Zoledronic Acid Solution for Infusion

Contains the active ingredient zoledronic acid (as monohydrate)

### Consumer Medicine Information

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

#### What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

#### What this medicine is used for

The name of your medicine is APO-Zoledronic Acid 4mg/5mL or APO-Zoledronic Acid 4mg/100mL. It contains the active ingredient zoledronic acid (as monohydrate).

It 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.

It 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.

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.

#### 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.

There is no evidence that this medicine is addictive.

#### Use in children

This medicine should not be used in children. The safety and effectiveness in children have not been established.

#### Before you take this medicine

##### When you must not take it

Do not take this medicine if:

- **You are pregnant.**  
Zoledronic acid may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**  
Zoledronic acid may pass into human breast milk.
- **You are hypersensitive to or have had an allergic reaction to, zoledronic acid, any of the ingredients listed at the end of this leaflet or any other bisphosphonates such as alendronate or risedronate.**

**If you are not sure whether you are allergic to other bisphosphonate medicines, talk to your doctor.**

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 or hayfever-like symptoms

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

##### Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have been treated with or are being treated with:
  - other medicines which contain zoledronic acid
  - other bisphosphonate medicines
  - diuretic therapy (commonly called 'fluid tablets').
2. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
3. You have or have had any medical conditions, especially the following:
  - 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.
4. You are currently receiving or are planning to receive dental treatment.

**It is advisable to have a dental check-up before starting zoledronic acid. Tell your dentist you may be receiving zoledronic acid.**

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. You may

need to have dental treatment completed before starting it.

5. You are planning to have surgery or an anaesthetic.
6. You are taking or are planning to take any other medicines, this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with zoledronic acid. These include:

- medicines that may affect your kidneys, such as fluid tablets
- aminoglycoside medicines, used to treat severe infections. The combination of aminoglycoside and bisphosphonate medicines may cause the level of calcium in the blood to become too low anti-angiogenic medicines as part of your cancer treatment. The combination of these medicines and bisphosphonate medicines 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, a medicine used in clinical trials to treat multiple myeloma
- loop diuretics, medicines used to treat high blood pressure or oedema.

If you are taking any of these you may need a different dose or you may need to take different medicines.

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

#### How this medicine is given

Zoledronic acid is given as a no less than 20 minute 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.

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 give you a lower dose if you have a mild kidney problem. Your doctor may also prescribe a daily calcium supplement and a multiple vitamin containing Vitamin D.

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

#### If you have too much (overdose)

**If you think that you or anyone else may have had too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**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.

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### **While you are being given this medicine**

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#### **Things you must do**

Tell your doctor that you are taking this medicine if:

- you have any dental symptoms including pain or unusual feeling in your teeth or gums, or any dental infections
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a blood test to make sure the treatment is working. Regular blood tests can also help detect side effects before they become serious.

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

#### **Things to be careful of**

Be careful when 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.

Many cancer medicines can cause 'dry mouth' which can lead to decay and other dental problems. Keep your mouth moist by drinking water.

#### **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
- 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.**

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### **Possible side effects**

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Tell your doctor as soon as possible if you do not feel well while you are taking zoledronic acid or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

#### **Tell your doctor if you notice any of the following:**

- short-lasting fever, sometimes with flu-like symptoms: such as chills; tiredness; fatigue; weakness; aches and pains, and joint pain and swelling
- redness, swelling or pain where the needle for the infusion was inserted
- upset stomach, abdominal pain, loss of appetite

- nausea (feeling sick) or vomiting
- dry or sore mouth
- constipation or diarrhoea
- swollen aching joints or muscles, pain in the bones
- swelling of fingers or lower legs due to fluid build up
- anxiety, confusion, difficulty sleeping
- headache, facial pain
- irritated eyes, blurred vision, eye pain, sensitivity to light, runny, itchy or swollen eyes
- changes in taste sensation
- cough
- slow heart beat
- increased sweating
- irregular heart beat
- difficulty breathing with wheezing or coughing.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These may be serious side effects. You may need urgent medical attention or hospitalisation:

- 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
- passing less urine than normal, blood in the urine
- 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.

Patients taking zoledronic acid may be at risk of unusual fracture of the thigh bone. Contact your doctor if you experience 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.

#### **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.

#### **Allergic reactions**

**If you think you are having an allergic reaction to zoledronic acid, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- 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.

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### **Storage and disposal**

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#### **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 its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay 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.

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### **Product description**

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

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

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.

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

It also contains the following inactive ingredients:

- mannitol
- sodium citrate
- water for injections.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

#### **Australian Registration Numbers**

APO-Zoledronic Acid 4mg/5mL concentrated injection (packs of 1, 4 or 10 vials): AUST R 190337

APO-Zoledronic Acid 4mg/100mL injection solution for infusion (packs of 1, 4 or 5 vials): AUST R 205927.

#### **Sponsor**

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