Zoledasta™ 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 Zoledasta™ . 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.

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 Zoledasta™. It contains the active ingredient zoledronic acid.

It is used to treat:

- treat osteoporosis in postmenopausal women to reduce the incidence of fractures
- treat osteoporosis in men and women over 50 years of age to reduce the incidence of additional fractures in patients who have had a hip fracture
- increase bone mineral density in men with osteoporosis
- increase bone mineral density in men and women with osteoporosis associated with long term steroid use, such as prednisone
- prevent bone mineral density loss caused by steroid use in men and women
- treat Paget's disease of bone in men and women.

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).

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

Zoledasta™ 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.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children. 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 have or have had any of the following:**

  - low levels of calcium in your blood

  - kidney problems

  - uveitis (inflammation of the inner eye).
- **You are pregnant.**

  Zoledasta™ may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**

  Zoledasta™ may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, zoledronic acid, other bisphosphonates, or any of the ingredients listed at the end of this leaflet.**

  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 hay fever-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:
- calcium or vitamin D deficiency
- you are unable to take daily calcium or vitamin D supplements
- surgery on your thyroid or parathyroid
- you have had sections of your intestine removed
- 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 your medicine. Tell your dentist you may be receiving Zoledasta™.

   A dental condition called jaw osteonecrosis has been reported in some patients being treated with Zoledasta™ or other drugs in the same class as your medicine. You may need to have dental treatment completed before starting it.
5. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
6. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
7. You are planning to have surgery or an anaesthetic.
8. You are currently receiving or are planning to receive dental treatment.
9. 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.

Taking other medicines

Some medicines may interact with Zoledasta™ .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.

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

Zoledasta™ is given as a no less than 20 minute infusion into a vein by your doctor or nurse once a year. You may also be given an infusion of fluids to ensure that you do not become dehydrated.

How much will you 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.

For osteoporosis, each dose of Zoledasta™ lasts one year. Your doctor will check your condition and may prescribe further annual doses.

For Paget's disease, treatment is a single infusion of Zoledasta™. In some cases re-treatment may be necessary. Your doctor will let you know if you need to be treated again.

Make sure you drink enough fluids before and after the treatment with this medicine 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.

If you take too much (overdose)

If you think that you or anyone else may have taken 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:

- 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 taking this medicine

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 of gums, or any dental infections
- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- 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.

Your doctor may occasionally do tests such as X-rays, bone density scans or blood tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

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

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 Zoledasta™ 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 Zoledasta™ . This is to reduce the risk of low calcium levels in your blood.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. If you are travelling home by car 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
- avoiding use of mouthwash that contains alcohol.

Keep your mouth moist by drinking water. 'Dry mouth' can lead to decay and other dental problems.

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Zoledasta™ 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 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
- palpitations (feeling of fast, forceful and/or irregular heartbeat), which may be accompanied by dizziness and breathlessness
- excessive sweating
- difficulty sleeping.

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 are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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 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).

Patients taking Zoledasta™ 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 Zoledasta™, 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, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

It is unlikely that you will have to store Zoledasta™ 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.

Product description

What Zoledasta™ looks like

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

Packs of 1, 3 and 5 vials

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

Ingredients

Each vial contains 5.33 mg of zoledronic acid (as monohydrate), equivalent to 5 mg of zoledronic acid in 100mL 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

Zoledasta: AUST R 205929

Sponsor

Apotex Pty Ltd
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