Zoledasta™ Solution for Infusion

Zoledronic acid (as 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 Zoledasta™. 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 using 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

Zoledasta™ 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.

Paget's disease is a chronic disorder which may affect various bones of the skeleton. Bone is a living tissue and is constantly being renewed. 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 broken bones.

How it works

Zoledasta™ works by slowing down the breaking down of bone, 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 this medicine for another reason.

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

This medicine is not addictive.

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

Before you use this medicine

When you must not take it

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

- zoledronic acid
- other bisphosphonates (e.g. 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, hay fever-like symptoms.

Do not use this medicine if you have or have had any of the following medical conditions:

- low levels of calcium in your blood
- kidney problems
- uveitis (inflammation of the inner eye)

Do not use this medicine if you are pregnant, trying to become pregnant or are breastfeeding.
Zoledasta™ may affect your developing baby if you take it during pregnancy. Zoledasta™ may also pass into human breast milk.

Do not use 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, your pharmacist can dispose of it.

If you are not sure whether you should use 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 been treated with or are being treated with:

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

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

- 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
- 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
- uveitis or iritis (inflammatory conditions of the eye).

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

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.

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 from your pharmacy, supermarket or health food shop.

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.

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, depending on your condition and if you are taking any other medicines.

Osteoporosis
Each dose of Zoledasta™ lasts one year. Your doctor will check your condition and may prescribe further annual doses.

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)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdose symptoms 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

If you get a headache, fever or other flu-like symptoms in the first three days after you are given Zoledasta™, take paracetamol if your doctor has told you to.
Some people get short-lasting flu-like symptoms after having Zoledasta™.Paracetamol can provide some relief.

If you are about to be started on any new medicine, tell 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.

Tell your doctor and dentist if you have any dental symptoms including pain or an unusual feeling in your teeth or gums,

loosening of a tooth and/or non-healing sores, discharge (pus or oozing), or any other dental infections.
A dental condition called jaw osteonecrosis has been reported, primarily in patients being treated with this type of medicine for other illnesses.

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

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

Go to your doctor regularly for a check-up.
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.

Your doctor may ask you to take calcium and vitamin D supplements.
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.
Zoledasta™ may cause dizziness in some people and affect the ability to drive or operate machinery. 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.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Zoledasta™.

All medicines can have side effects.Sometimes they are serious but most of the time they are not.

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

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 infusion needle 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, sensitivity to light, or conjunctivitis (yellow, crusty discharge in the eyes)
- 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, tell your doctor or nurse immediately:

- 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 (signs of an allergic reaction)
- muscle spasms, numbness or tingling sensation, especially around the mouth, shortness of breath (signs of low blood calcium)
- muscle problems and weakness, confusion, irritation, and delirium (signs of low blood phosphorus)
- decreased urine output (signs of kidney impairment)
- 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 (signs of bone damage in the jaw)

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

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.
Patients taking Zoledasta™ may be at risk of unusual 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. Some of these (e.g. effects on kidney function and on the level of calcium in the blood) can only be found by having regular blood tests.

Storage and disposal

Storage

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

Your pharmacist can safely dispose of any remaining medicine.

Product description

What it looks like

Clear, colourless, sterile solution packaged in glass vials.

AUST R 205929.

Each pack contains 1 vial. Multipacks contain 3 or 6 packs, each containing 1 vial* 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:

- mannitol
- sodium citrate dihydrate
- water for injections

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

Sponsor

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