

ZOLEDRONIC ACID VIATRIS

Zoledronic Acid Solution for Infusion 5 mg/100 mL



What is in this leaflet

Please read this leaflet carefully before you start being given Zoledronic Acid Viatrix.

This leaflet answers some common questions about Zoledronic Acid Viatrix.

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 being given Zoledronic Acid Viatrix against the benefits they expect it will have for you.

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

Keep this leaflet. You may need to read it again.

What Zoledronic Acid Viatrix is used for

Zoledronic Acid Viatrix is used to:

- treat osteoporosis in postmenopausal women and men
- prevent additional fractures in men or women who have recently had a hip fracture
- treat or prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone
- treat Paget's disease of bone.

Zoledronic Acid Viatrix contains the active ingredient zoledronic acid. It belongs to a group of medicines called bisphosphonates.

It 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.

Your doctor may have prescribed this medicine for another reason.

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

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

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

Before you are given Zoledronic Acid Viatrix

When you must not have it

Do not have Zoledronic Acid Viatrix if you have an allergy to:

- any medicine containing zoledronic acid
- any of the ingredients listed at the end of this leaflet
- any other bisphosphonate medicine such as alendronate or risedronate.

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 Zoledronic Acid Viatrix 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 Zoledronic Acid Viatrix.

Do not have this medicine if you are pregnant.

There is no information on use of this medicine in pregnancy.

Do not breastfeed while you are having treatment with this medicine.

It is not known if the active ingredient in Zoledronic Acid Viatrix passes into breast milk and there is a possibility that your baby may be affected.

Do not have 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 be given this medicine, talk to your doctor.

Before you have it

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

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

- another zoledronic acid product (used for oncology treatment)
- another bisphosphonate medicine prior to Zoledronic Acid Viatrix
- diuretic treatment (commonly called 'fluid tablets').

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

- kidney problem
- calcium deficiency
- vitamin D deficiency
- unable to take daily calcium or vitamin D supplements
- some or all of your parathyroid or thyroid glands in your neck surgically removed
- sections of your intestine removed
- pain, swelling or numbness of the jaw or loosening of a tooth or any other oral issues
- 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 need to have any dental treatment or dental surgery.

Your doctor will check your oral health before you start treatment with Zoledronic Acid Viatris. 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 Zoledronic Acid Viatris.

If you have not told your doctor about any of the above, tell them before you start treatment with Zoledronic Acid Viatris.

Taking other medicines

Tell your doctor 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.

You should also tell any health professional who is prescribing a new medication for you that you are being given Zoledronic Acid Viatris.

Some medicines and Zoledronic Acid Viatris may interfere with each other. These include:

- medicines that may affect your kidneys such as fluid tablets
- aminoglycoside medicines used to treat severe infections.

These medicines may be affected by Zoledronic Acid Viatris 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.

How Zoledronic Acid Viatris is given

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They 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 treatment with Zoledronic Acid Viatris 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 Zoledronic Acid Viatris.

How it will be given

Zoledronic Acid Viatris 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 100 ml infusion will last at least 15 minutes.

How long treatment will last

For osteoporosis:

Each dose of Zoledronic Acid Viatris lasts one year. Your doctor will check your condition and may prescribe further annual doses.

For Paget's disease:

Each dose of Zoledronic Acid Viatris may work for longer than one year. Your doctor will let you know if you need to be treated again.

While you are being given Zoledronic Acid Viatris

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Zoledronic Acid Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you get a headache, fever or other flu-like symptoms in the first three days after you are given Zoledronic Acid Viatris, take paracetamol if your doctor has told you to.

Some people get short-lasting flu-like symptoms after having Zoledronic Acid Viatris. 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 Zoledronic Acid Viatris 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 Zoledronic Acid Viatris to reduce the risk of low calcium levels in your blood.

If you become pregnant while having treatment with this medicine, tell your doctor immediately.

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 the medicine is working and to prevent unwanted side effects.

Tell your doctor and dentist immediately about any dental symptoms you get while you are being treated with Zoledronic Acid Viatrix. 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.

Things to be careful of

Be careful driving or operating machinery until you know how Zoledronic Acid Viatrix affects you.

This medicine may cause dizziness, light headedness or sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you have too much (overdose)

As Zoledronic Acid is usually given to you under supervision of a healthcare professional, it is very unlikely that you will receive an overdose.

In the case of an overdose, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you have been given too much Zoledronic Acid Viatrix. Do this even if there are no signs of

discomfort or poisoning. You may need urgent medical attention.

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 low.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Zoledronic Acid Viatrix.

This medicine helps most people with osteoporosis or Paget's disease, 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 treatment if you get some of the side effects.

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 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 loss 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 in 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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, throat, lips, tongue and 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
- signs of bone damage in the jaw (osteonecrosis), such as 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.

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

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. Tell your doctor if you notice any other effects.

Some of these side effects (for example, effects on kidney function and on the level of calcium in the blood) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After having Zoledronic Acid Viatris

Storage

It is unlikely you will have to store Zoledronic Acid Viatris at home.

If you do have to store it:

Store the medicine in a cool dry place where the temperature stays below 25°C

Do not store Zoledronic Acid Viatris 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 it 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 you no longer need this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Zoledronic Acid Viatris is a clear, colourless solution supplied in a polypropylene infusion bag with a twist off port, overwrapped with an aluminium pouch.

Pack size is a single bag of 100 mL.

Ingredients

Active ingredient:

Zoledronic Acid Viatris contains 5 mg of zoledronic acid (anhydrous) as the active ingredient.

Inactive ingredients:

Zoledronic Acid Viatris also contains:

- mannitol
- sodium citrate
- water for injections.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Zoledronic Acid Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

11 February 2025.
(Based on datasheet dated 11 February 2025)