

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ZOLEDRONIC ACID MYLAN

Zoledronic Acid Concentrate for Infusion 4mg/5mL



What is in this leaflet

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

This leaflet answers some common questions about Zoledronic Acid Mylan.

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 Mylan 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 with the medicine. You may need to read it again.

What Zoledronic Acid Mylan is used for

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

Zoledronic Acid Mylan 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.

Zoledronic Acid Mylan contains the active ingredient zoledronic acid. It 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 levels.

Your doctor may have prescribed it 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.

This medicine is not addictive.

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

Before you are given Zoledronic Acid Mylan

When you must not be given it

Do not use Zoledronic Acid Mylan if you have an allergy to:

- any medicine containing zoledronic acid
- any other bisphosphonate medicine
- any of the ingredients listed at the end of this leaflet.

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.

Patients with severe kidney problems should not use this medicine.

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are using this medicine.

It is unknown whether zoledronic acid passes into 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, return it to your pharmacist for disposal.

If you are not sure whether you should start using 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 problems
- take any other bisphosphonate medicines
- heart condition, such as heart failure
- asthma and are also allergic to aspirin
- thyroid surgery
- pain or swelling of the mouth, in particular the teeth, gums or jaw
- femoral fractures and/or thigh, hip or groin pains.

If you have not told your doctor about any of the above, tell him/her before you start using Zoledronic Acid Mylan.

Ensure sufficient intake of fluid (water) prior to infusions as directed by your doctor as this will help prevent dehydration.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get 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 Mylan.

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

- medicines that may have side effects on your kidneys
- aminoglycoside antibiotics used to treat severe infections
- medicines, such as calcitonin, used in the treatment of patients with osteoporosis or high blood calcium levels
- loop diuretics, medicines used to treat high blood pressure or oedema
- anti-angiogenic medicines used in the treatment of cancer
- thalidomide, a medicine used in the treatment of multiple myeloma (cancer of the blood).
- Aclasta, a medicine which also contains zoledronic acid, and is used to treat osteoporosis..

These medicines may be affected by Zoledronic Acid Mylan 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 Mylan is given

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

They may differ from the information contained in this leaflet.

How much you need

Your doctor will decide on the dose and length of time that you will

receive Zoledronic Acid Mylan. Use the medicine for as long as the doctor recommends.

In patients with high blood calcium levels, the usual dose of Zoledronic Acid Mylan is 4 mg, given as a single infusion.

The usual dose of Zoledronic Acid Mylan used to treat patients with bone cancer is 4 mg, given as an infusion every 3 to 4 weeks. The dose of Zoledronic Acid Mylan may be lowered depending on your kidney function. These individuals may also receive a daily calcium supplement and multivitamin containing Vitamin D.

During treatment with Zoledronic Acid Mylan, you will undergo blood tests to monitor blood chemical levels to make sure the medicine is not affecting your kidneys.

How it will be given

Zoledronic Acid Mylan must only be given by a doctor or a nurse.

Zoledronic Acid Mylan is given as a 15 minute infusion into a vein.

You may also be given an infusion of fluids to ensure that you do not become dehydrated.

How long to use it

Continue using your medicine for as long as your doctor tells you.

While you are using Zoledronic Acid Mylan

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 Mylan.

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

Tell your doctor or dentist immediately about any dental symptoms including pain,

swelling, or unusual feeling in your teeth or gums, or non-healing of sores or discharge in your mouth, or any dental infections.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

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

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

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

- brush 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
- avoiding use of mouthwash that contains alcohol.

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

Things you must not do

Do not use Zoledronic Acid Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness, tiredness or blurred vision 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 Mylan is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Tell your doctor if you have any of the following symptoms. They may mean that the level of calcium in your blood has fallen too far.

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

In case of an overdose, immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, if you think that you have been given too much Zoledronic Acid Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

This medicine helps most people with high blood calcium levels, but it may have unwanted side effects. 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:

- fever or high temperature of short duration, with flu-like symptoms such as fatigue (tiredness), weakness, chills and joint aches/pains/swelling
- skin redness, swelling, itching or pain, in particular where the infusion needle was inserted
- swelling of the fingers, hands, feet or ankles
- tingling or numbness of the hands or feet
- increased sensitivity to touch
- feeling sick (nausea) or vomiting
- constipation, diarrhoea, indigestion or abdominal pain
- loss of appetite
- dry or sore mouth
- conjunctivitis or swollen itchy eyes that can release a runny discharge
- weight gain
- bone pain
- difficulty sleeping or excessive sleepiness
- headache
- cough
- taste disturbances or loss of taste
- excessive sweating.

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

- joint stiffness or pain, particularly in the thigh, hip or groin
- slow or irregular heart beat
- shortness of breath
- anxiety, confusion, dizziness

- fainting
- passing less or excessively more urine than normal
- blurred vision and/or sensitivity to light.

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

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

- signs of an allergic reaction, such as 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
- persistent flu-like symptoms such as high temperature, chills and fatigue
- chest pain
- tremors or muscle spasms
- seizures or convulsions
- blood in the urine
- non-healing sores/ulcers and/or pain in the mouth, gums or jaw, including 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.

Some of these side effects (for example, effects on kidney function, changes in blood pressure or platelet count) can only be found when your doctor does tests from time to time to check your progress.

After using Zoledronic Acid Mylan

Storage

This medicine should be kept in the packaging until it is time to use it.

Zoledronic Acid Mylan should be kept in a cool dry place where the temperature stays below 25°C.

Do not store Zoledronic Acid Mylan 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 your doctor tells you to stop taking 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 Mylan is a clear, colourless solution.

Ingredients

Active ingredient:

Zoledronic Acid Mylan contains 4 mg of zoledronic acid as the active ingredient.

Inactive ingredients:

Zoledronic Acid Mylan also contains:

- sodium citrate
- sodium hydroxide
- hydrochloric acid
- water for injection.

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

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

11 September 2019

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