

Zometa®

zoledronic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zometa.

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

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au. or www.medsafe.govt.nz (New Zealand).

Those updates may contain important information about the medicine and its use of which you should be aware.

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 having Zometa against the benefits they expect it will provide.

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

Keep this leaflet.

You may need to read it again.

What Zometa is used for

- Zometa 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. Zometa 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.

- Zometa 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 it for another purpose.

Zometa is only available with a doctor's prescription. It is not addictive.

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

Before you have Zometa

When you must not have it

Do not have Zometa if you have ever had an allergic reaction to:

- zoledronic acid (the active ingredient in Zometa) or to any of

the other ingredients listed at the end of this leaflet

- any other bisphosphonate medicine.

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 can cause breathing difficulties in people with asthma who are allergic to aspirin. It is not known whether Zometa can have this effect.

Do not have Zometa if you are pregnant.

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

Do not breast-feed while you are having treatment with Zometa.

It is not known if the active ingredient, zoledronic acid, passes into the breast milk and could affect your baby.

If you are being treated with Zometa (zoledronic acid), you should not be treated with Aclasta concomitantly.

Do not have Zometa after the expiry date printed on the label or if the packaging is torn or shows signs of tampering.

In that case, return the medicine to your pharmacist.

Before you start to have it

Tell your doctor if:

- you have a kidney or liver problem
- you have a heart condition

- you have asthma and are also allergic to aspirin
- you have had surgery on your thyroid
- you take any other bisphosphonates
- you had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth or any other oral issues
- you had or have joint stiffness, aches and pains and difficulty in movement (especially of the hip or thigh) or pain around the external ear canal
- you take medication that may lower calcium levels in your blood and you may require calcium with Vitamin D supplements.

It is advisable to have a dental check-up before starting on Zometa and regular dental check-ups while on Zometa. Tell your dentist you may be receiving Zometa.

Tell your doctor if you need to have any dental treatment or dental surgery. If you are undergoing dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Zometa.

A dental condition called jaw osteonecrosis has been reported in some patients being treated with Zometa or with other drugs in the same class as Zometa. You may need to have dental treatments completed before starting it.

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

Your doctor may want to take special precautions if you have any of the above conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Zometa may interfere with each other. These include:

- medicines that may have side effects on your kidneys
- 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).
- Aclasta or any other bisphosphonates, such as Actonel, Fosamax
- loop diuretics, medicines used to treat high blood pressure or oedema
- calcitonin (a type of medicine used to treat post-menopausal osteoporosis and high calcium levels).

You may need to take different amounts of these medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you have Zometa.

How Zometa is given

How it will be given

Zometa 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 much you need

To lower the amount of calcium in the blood, the usual dose of Zometa 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.

You will have a blood test before each dose of Zometa to make sure the medicine is not affecting your kidneys.

If you have too much

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.

While you are having Zometa

Things you must do

Make sure you follow your doctor's instructions carefully and keep all appointments.

You will need regular blood tests to make sure the treatment is working. Regular blood tests can also find side effects before they become serious.

Tell your doctor immediately if you become pregnant while having treatment with Zometa.

Your doctor can discuss with you the risks of having it while you are pregnant.

Tell your doctor and dentist immediately about any dental symptoms including pain, swelling or unusual feeling in your teeth or gums, or non-healing of sores or discharge or any dental infections.

A dental condition called jaw osteonecrosis has been reported in some patients being treated with Zometa or other drugs in the same class as Zometa.

Tell your dentist that you are being treated with Zometa.

Your dentist may need to take special precautions.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Zometa.

Tell any other doctor or pharmacist who treats you that you are having Zometa.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are having Zometa until you know how it affects you. If you are returning home immediately 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
- keeping your mouth moist by drinking water (many cancer medicines can cause "dry mouth" which can lead to decay and other dental problems)
- 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 or dentist immediately.

Side effects

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

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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- short-lasting fever, sometimes with flu-like symptoms such as chills, tiredness, weakness and aches and pains
- redness, swelling or pain where the needle for the infusion was inserted
- tingling or numbness of the hands or feet
- 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, hands, feet, ankles 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, red or swollen eyes
- changes in taste sensation
- cough
- slow heart beat
- increased sweating
- irregular heart beat
- difficulty breathing with wheezing or coughing
- lung disease
- weight increased
- pain, weakness or discomfort in your thigh, hip or groin. Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur. Contact your doctor if you experience this as it may be an early sign of a possible fracture of the thigh bone.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue

or other part of the body; shortness of breath, wheezing or troubled breathing

- 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
- 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
- seizures
- spasm and twitching
- passing less urine than normal, blood in the urine
- pain in the mouth, teeth or jaw, sores or non-healing sores in the mouth or discharge, swelling, dry mouth, numbness or a feeling of heaviness in the jaw ("heavy jaw feeling") or loosening of a tooth. These symptoms could be a sign of a jaw-bone problem known as jaw osteonecrosis
- passing large amount of urine (that can lead to dehydration), bone pain and muscle weakness (can be a problem with how the kidneys are working).

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed here may happen in some people. Some of these (e.g. effects on kidney function and on the level of some chemicals in the blood) can only be found by laboratory testing.

After having Zometa

Storage

If you are keeping a supply of Zometa at home:

- Store the medicine in a cool dry place below 30°C.
- Do not store Zometa or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot days.

Keep the medicine where young 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 Zometa or the expiry date has passed, return any unused medicine to your pharmacist.

Product description

What it looks like

Zometa concentrated injection is packaged in plastic vials containing the active ingredient, zoledronic acid, in 5 mL solution.

Zometa ready to use injection solution is packaged in a plastic vial containing the active ingredient, zoledronic acid, in 100 mL solution. (Not supplied in New Zealand)

Ingredients

Each vial of Zometa concentrated injection contains 4 mg of zoledronic acid. The vials also contain mannitol, sodium citrate and water for injections.

Each vial of Zometa injection solution contains 4 mg of zoledronic acid. The vials also contain mannitol, sodium citrate and water for injections. (Not supplied in New Zealand)

Sponsor

Zometa is supplied in Australia by:
 Novartis Pharmaceuticals Australia Pty Limited
 (ABN 18 004 244 160)
 54 Waterloo Road

North Ryde NSW 2113
 Telephone: 1-800-671-203

Zometa is supplied in New Zealand by:

Novartis New Zealand Limited
 109 Carlton Gore Road
 Newmarket
 Auckland 1023
 New Zealand

PO Box 99102
 Newmarket
 Auckland 1149
 Telephone: 0800 354 335

® = Registered Trademark.

This leaflet was prepared in June 2016.

Australian Registration Number

Zometa concentrated injection 4 mg/5 mL AUST R 90882

Zometa injection solution 4 mg/100 mL AUST R 192265

(zom270616c.doc) based on PI
 (zom270616i.doc)