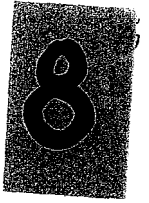


Zometa®

zoledronic acid



Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zometa.

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 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.

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

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.

- thalidomide, a medicine used in clinical trials to treat multiple myeloma

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 will be given by intravenous infusion into a vein. ~~The dry powder in the vial is dissolved in sterile water and then put into an intravenous drip.~~

Zometa is given as a 15- minute infusion.

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. If the calcium level starts to rise again, another infusion can be given, usually with an increased dose of 8 mg Zometa.

To treat cancer in the bone, the usual dose is 4 mg, given as an infusion every 3 to 4 weeks. 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 lightheadedness, 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. You doctor can discuss with you the risks of having it while you are pregnant.

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, dentist 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.

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
- 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 or lower legs due to fluid buildup
- anxiety, confusion, difficulty sleeping
- headache
- irritated, red, runny or itchy eyes, blurred vision
- changes in taste sensation
- cough
- slow heart beat
- increased sweating

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 lightheadedness, 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
- passing less urine than normal, blood in the urine

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 degrees 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 powder for injection is packaged in glass vials containing the active ingredient, zoledronic acid, in a dry powder form. An ampoule containing 5 mL of water for injections, used for dissolving the powder, comes with each vial. Packs containing 1 vial.

Zometa liquid concentrate is packaged in plastic vials containing the active ingredient, zoledronic acid, in 5 mL solution. Packs containing 1, 4, 10 vials.

Ingredients

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

Sponsor

Zometa is supplied in Australia by:
Novartis Pharmaceuticals Australia Pty Limited
(ACN 004 244 160)
54 Waterloo Road
North Ryde NSW 2113
Telephone 1-800-671-203

® = Registered Trademark

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Australian Registration Number.
Zometa 4 mg vial powder for injection -AUST R 76928

Zometa concentrated injection - 4 mg/ 5 mL AUST R 90882