

Deztron

contains the active ingredient zoledronic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEZTRON. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. Your doctor has weighed the risks of you taking DEZTRON against the benefits they expect it will have for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DEZTRON is used for

DEZTRON 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. DEZTRON belongs to a group of medicines called bisphosphonates, which strongly bind to bone. These medicines work by slowing down the rate of bone change and help to restore the amount of calcium in the blood to normal.
- 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 DEZTRON has been prescribed for you.

Your doctor may have prescribed DEZTRON for another purpose.

DEZTRON 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 are given DEZTRON

When you must not have it

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

- zoledronic acid (the active ingredient in DEZTRON) 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 skin rash, itching or hives, swelling of the face, lips or tongue or other parts of the body, which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

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 DEZTRON can have this effect.

Do not have DEZTRON if you are pregnant.

There is no information on the use of DEZTRON during pregnancy.

Do not have DEZTRON if you are breastfeeding.

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 DEZTRON (zoledronic acid), you should not be treated with Aclasta concomitantly.

Do not have DEZTRON if the expiry date (Exp.) 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 take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or breastfeed.

Tell your doctor if you have, any medical conditions, especially the following:

- kidney or liver problems
- a heart condition
- asthma and are allergic to aspirin
- had surgery on your thyroid
- had or have pain in teeth, gum 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 DEZTRON and regular dental checkups while on DEZTRON Tell your dentist you may be receiving DEZTRON.

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 DEZTRON.

A dental condition called jaw osteonecrosis has been reported in some patients being treated with DEZTRON or with other medicines in the same class as DEZTRON. You may need to have any necessary 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 any that you buy without a prescription from a

pharmacy, supermarket or health food shop.

Some medicines may be affected by DEZTRON, or may affect how well it works. 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 DEZTRON.

How DEZTRON will be given

How it will be given

DEZTRON 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 DEZTRON 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 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 DEZTRON to make sure the medicine is not affecting your kidneys.

If you are given too much DEZTRON (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

While you are being given DEZTRON

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 all the doctors, dentists and pharmacists who are treating you that you are being given DEZTRON.

If you become pregnant while being given DEZTRON, tell your doctor immediately.

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 or unusual feeling in your teeth or gums, or any dental infections.

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

Tell your dentist that you are being treated with DEZTRON.

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 being given DEZTRON.

Things to be careful of

Be careful driving, operating machinery or performing jobs that require you to be alert until you know how DEZTRON 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 DEZTRON.

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 this list 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 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 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 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 longterm 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 the 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 parts 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 lightheadness, 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, swelling or sores inside the mouth, numbness or a "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 effects can be serious. You may need urgent medical attention.

Tell your doctor if you notice anything 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 using DEZTRON

Storage

If you are keeping a supply of DEZTRON at home:

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

If you keep DEZTRON at home, 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 DEZTRON, or the expiry date has passed, return any unused medicine to your pharmacist

Product description

What it looks like

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

Ingredients

The active ingredient in DEZTRON is zoledronic acid. Each DEZTRON vial contains 4 mg of zoledronic acid in a 5 mL solution.

The solution also contains:

- mannitol
- sodium citrate
- water for injections.

Supplier

Medsurge Healthcare Pty Ltd
Unit 2, 6-7 Gilda Court
MULGRAVE
VICTORIA 3170

Australian registration numbers:
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