

# ZOLEDRONIC ACID ACCORD

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Zoledronic Acid Accord?

Zoledronic Acid Accord contains the active ingredient zoledronic acid. This medicine can be used:

- To lower the amount of calcium in the blood when it becomes too high, as may happen in some forms of cancer.
- To slow down the spread of cancers in bone, helping to prevent changes to the bones that may cause them to weaken.
- As an additional treatment for women with early breast cancer, who are in established menopause.

For more information, see Section [1. Why am I using Zoledronic Acid Accord?](#) in the full CMI.

### 2. What should I know before I'm given Zoledronic Acid Accord?

Do not use if you are allergic to zoledronic acid, any of the ingredients listed at the end of this leaflet or any other bisphosphonate medicine.

Talk to your doctor if you have any other medical conditions, take any other medicines, plan to have dental treatment, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I'm given Zoledronic Acid Accord?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Zoledronic Acid Accord and affect how it works.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Zoledronic Acid Accord given?

Zoledronic Acid Accord is an injection and will be given to you by your doctor.

More instructions can be found in Section [4. How is Zoledronic Acid Accord given?](#) in the full CMI.

### 5. What should I know while being given Zoledronic Acid Accord?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any other doctors, nurses or pharmacists who treat you that you are taking this medicine</li><li>• Tell your doctor immediately if you become pregnant while taking this medicine</li><li>• Tell your doctor if you experience any of the side effects listed in the CMI</li></ul>
<b>Things you should not do</b>	Do not receive Zoledronic Acid Accord if you are allergic to zoledronic acid, any of the ingredients listed at the end of this leaflet or any other bisphosphonate medicine.
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how Zoledronic Acid Accord affects you.

For more information, see Section [5. What should I know while being given Zoledronic Acid Accord?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the common and serious side effects are included below in the CMI. Speak to your doctor if you have side effects and they worry you.

Symptoms of a serious allergic reaction are:

- skin rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ZOLEDRONIC ACID ACCORD

Active ingredient: *zoledronic acid*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Zoledronic Acid Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Zoledronic Acid Accord.**

Where to find information in this leaflet:

- [1. Why am I using Zoledronic Acid Accord?](#)
- [2. What should I know before I'm given Zoledronic Acid Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Zoledronic Acid Accord given?](#)
- [5. What should I know while using Zoledronic Acid Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Zoledronic Acid Accord?

**Zoledronic Acid Accord contains the active ingredient zoledronic acid.** Zoledronic Acid Accord 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 reduce the amount of calcium in the blood.

Some cancers can speed up normal changes in bone so that the amount of calcium released from the bones into the blood is increased.

Zoledronic Acid Accord can be used to lower the amount of calcium in the blood when it becomes too high, as may happen in some forms of cancer.

Zoledronic Acid Accord can also be 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.

Zoledronic acid can be used as an additional treatment for women with early breast cancer who are in established menopause.

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

## 2. What should I know before I'm given Zoledronic Acid Accord?

### Warnings

**Do not receive Zoledronic Acid Accord if:**

- you are allergic to zoledronic acid, any of the ingredients listed at the end of this leaflet or any other bisphosphonate medicine

**Check with your doctor if you have or have had:**

- a kidney or liver problem
- a heart condition
- asthma and are also allergic to aspirin
- surgery on your thyroid
- you take any other bisphosphonates or other strengths of zoledronic acid
- 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
- 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

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

Other bisphosphonate medicines can cause breathing difficulties in people with asthma who are allergic to aspirin. It is not known whether zoledronic acid can have this effect.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether Zoledronic Acid Accord passes into breast milk. You should not breastfeed during treatment with Zoledronic Acid Accord.

Your doctor will discuss the risks and benefits of using Zoledronic Acid Accord if you are pregnant or breast-feeding.

### General

If you are being treated with Zoledronic Acid Accord you should not be treated with other strengths of zoledronic acid concomitantly.

It is advisable to have a dental check-up before starting on Zoledronic Acid Accord. Tell your dentist you may be receiving Zoledronic Acid Accord.

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 Zoledronic Acid Accord.

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

Zoledronic Acid Accord. 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.

### 3. What if I am taking other medicines?

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

**Some medicines and Zoledronic Acid Accord 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)
- any other medicine containing zoledronic acid or other bisphosphonates, such as risedronate, alendronate
- loop diuretics, medicines used to treat high blood pressure or oedema
- thalidomide, use to treat multiple myeloma
- calcitonin, a type of medicine used to treat post-menopausal osteoporosis and high calcium levels

You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Zoledronic Acid Accord.**

### 4. How is Zoledronic Acid Accord given?

#### How it will be given

Treatment with Zoledronic Acid Accord will be under the supervision of a doctor. Your treatment with Zoledronic Acid Accord may be given to you by a doctor or nurse. Zoledronic Acid Accord solution is given as an infusion into your vein.

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

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

#### How much you will be given

To lower the amount of calcium in the blood, the usual dose is 4 mg, given as a single infusion.

To treat cancer in the bone, the usual dose is 4 mg, given every 3 to 4 weeks.

When given as an additional treatment for women with early breast cancer, the recommended dose of 4 mg, given

as an infusion every 6 months for 3 years or every 3 months for 2 years.

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 multivitamin containing Vitamin D.

#### If you are given too much

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much Zoledronic Acid Accord.

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

### 5. What should I know while being given Zoledronic Acid Accord?

#### Things you should do

Tell any other doctors, nurses or pharmacists who treat you that you are taking this medicine. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Zoledronic Acid Accord.

If you become pregnant while taking this medicine, tell your doctor immediately. Your doctor can discuss with you the risks of continuing treatment while you are pregnant.

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

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 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 zoledronic acid or other drugs in the same class as zoledronic acid.

Tell your dentist that you are being treated with Zoledronic Acid Accord.

Your dentist may need to take special precautions.

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.

## Driving or using machines

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

If you are returning home immediately after the infusion, arrange to have someone else drive.

## Looking after your medicine

The hospital will store Zoledronic Acid Accord under the correct conditions.

## Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Zoledronic Acid Accord that may be left over.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>• short-lasting fever, sometimes with flu-like symptoms such as chills, tiredness, weakness and aches and pains</li> <li>• redness, swelling or pain where the needle for the infusion was inserted</li> <li>• tingling or numbness of the hands or feet</li> <li>• upset stomach, abdominal pain, loss of appetite</li> <li>• nausea (feeling sick) or vomiting</li> <li>• dry or sore mouth</li> <li>• constipation or diarrhoea</li> <li>• swollen aching joints or muscles, pain in the bones</li> <li>• swelling of fingers, hands, feet, ankles or lower legs due to fluid build up</li> <li>• anxiety, confusion, difficulty sleeping</li> <li>• headache, facial pain</li> <li>• irritated eyes, blurred vision, eye pain, sensitivity to light, runny, itchy or swollen eyes</li> <li>• changes in taste sensation</li> <li>• cough</li> <li>• slow heart beat</li> <li>• increased sweating</li> <li>• irregular heart beat</li> <li>• difficulty breathing with wheezing or coughing</li> <li>• lung disease</li> <li>• weight increased</li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you</b></p>

<ul style="list-style-type: none"> <li>• 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</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue, throat or other part of the body; shortness of breath, wheezing or difficulty breathing</li> <li>• 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</li> <li>• 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</li> <li>• chest pain</li> <li>• seizures</li> <li>• spasm and twitching</li> <li>• passing less urine than normal, blood in the urine</li> <li>• 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)</li> <li>• 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)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur 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.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

It is not addictive.

### What Zoledronic Acid Accord contains

<b>Active ingredient (main ingredient)</b>	zoledronic acid
<b>Other ingredients (inactive ingredients)</b>	mannitol sodium citrate dihydrate water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Zoledronic Acid Accord looks like

Zoledronic Acid Accord is a clear colourless solution supplied in a plastic vial in packs of 1.

(4 mg/5 mL: AUST R 223405).

### Who distributes Zoledronic Acid Accord

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

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