

Zoledronic Acid SUN

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 SUN?

Zoledronic Acid SUN contains the active ingredient zoledronic acid. Zoledronic Acid SUN is used to treat osteoporosis in postmenopausal women and in men and also used to treat Paget's disease of bone.

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

2. WHAT SHOULD I KNOW BEFORE I USE ZOLEDRONIC ACID SUN?

Do not use if you have ever had an allergic reaction to zoledronic acid or any of the ingredients listed at the end of the CMI or any other bisphosphonate medicine. **Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

3. What if I am taking other medicines?

Some medicines may interfere with Zoledronic Acid medicine and affect how it works. These include: medicines that may affect your kidneys such as fluid tablets or aminoglycoside medicines used to treat severe infections. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. HOW DO I USE ZOLEDRONIC ACID SUN?

Zoledronic Acid SUN will be given to you by infusion into a vein by your doctor or nurse once a year. The infusion will take at least 15 minutes. More instructions can be found in Section [4. How do I use Zoledronic Acid SUN?](#) in the full CMI.

5. What should I know while using this medicine?

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| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Zoledronic Acid SUN.If you get a headache, fever or other flu-like symptoms in the first three days after you are given Zoledronic Acid SUN, take paracetamol if your doctor has told you to. |
| Things you should not do | <ul style="list-style-type: none">Do not have Zoledronic Acid SUN if you have low levels of calcium in your blood.Do not have Zoledronic Acid SUN if you are pregnant.Do not breast-feed while you are having treatment with Zoledronic Acid SUN. |
| Driving or using machines | Be careful driving or operating machinery until you know how Zoledronic Acid SUN affects you. |
| Looking after your medicine | Store the medicine in a cool dry place at room temperature. |

For more information, see Section [5. What should I know while using this medicine?](#) in the full CMI.

6. Are there any side effects?

Some common side effects are fever, upset stomach, vomiting, diarrhea, dry mouth, tiredness, pain in the back, neck and shoulder, joint stiffness, and swollen fingers to name a few. 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 SUN

Active ingredient(s): *zoledronic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **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 this medicine.**

Where to find information in this leaflet:

- [1. Why am I using Zoledronic Acid SUN?](#)
- [2. What should I know before I use Zoledronic Acid SUN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZOLEDRONIC ACID SUN?](#)
- [5. What should I know while using this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. WHY AM I USING ZOLEDRONIC ACID SUN?

The active ingredient in Zoledronic Acid SUN is zoledronic acid, which belongs to a group of medicines called bisphosphonates.

Zoledronic Acid SUN is used to treat osteoporosis in postmenopausal women and in men, to prevent additional fractures in men or women who have recently had a hip fracture, or to treat or prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone.

Zoledronic Acid SUN is also used to treat Paget's disease of bone.

Osteoporosis is a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break. This is common in women after menopause, when a woman's ovaries stop producing the female hormone, oestrogen, which keeps bones healthy. It also occurs in men and women with increasing age. Broken bones may result from injury or simple falls. Breaks may occur during normal everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone. Fractures in people with osteoporosis usually occur at the hip, spine or wrist. These can lead not only to pain, but also to considerable deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

Paget's disease is a chronic disorder which may affect various bones of the skeleton. Bone is a living tissue and, just like other parts of the body, it is constantly being renewed. This process is called bone remodelling.

In Paget's disease, the bone material breaks down more quickly than usual, and new bone material grows more quickly than usual and in a disordered way. The new bone that is formed may be thicker but weaker than normal, which can cause pain and may lead to fractures (broken bones).

2. WHAT SHOULD I KNOW BEFORE I USE ZOLEDRONIC ACID SUN?

Warnings

Do not use Zoledronic Acid SUN if:

- you are allergic to zoledronic acid, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- any other bisphosphonate medicine such as alendronate (e.g. Fosamax) or risedronate (e.g. Actonel).

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 have been shown to cause breathing difficulties in people with asthma who are allergic to aspirin.

Do not have Zoledronic Acid SUN if you have low levels of calcium in your blood.

Your doctor may do a blood test to check your calcium levels before you have zoledronic acid.

Do not have Zoledronic Acid SUN if you are pregnant.

Do not breast-feed while you are having treatment with Zoledronic Acid SUN.

Do not have Zoledronic Acid SUN 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.

If you are not sure whether you should be given this medicine, talk to your doctor.

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 or pharmacist if you are pregnant or intend to become pregnant.

Do not have Zoledronic Acid SUN 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 Zoledronic Acid SUN.

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

Tell your doctor if you have been or are being treated with:

- Zometa® which contains the same active ingredient as in Zoledronic Acid SUN
- other medications for the treatment of cancer which contains the same active ingredient as in Zoledronic Acid SUN
- another bisphosphonate medicine prior to Zoledronic Acid SUN
- diuretic therapy (commonly called 'fluid tablets')

Tell your doctor if:

- you have a kidney problem. This medicine is not suitable for some people with a kidney problem.
- you have a calcium deficiency or a vitamin D deficiency
- you are unable to take daily calcium or vitamin D supplements
- you have had some or all of your parathyroid or thyroid glands in your neck surgically removed
- you have had sections of your intestine removed
- you have or have had pain, swelling or numbness of the jaw or loosening of a tooth
- you are under dental treatment or will undergo dental surgery. Your doctor will check your oral health before you start treatment with Zoledronic Acid SUN. Discuss with him or her any planned dental surgery such as a tooth extraction. Tell your dentist that you are being treated with Zoledronic Acid SUN.
- you have or have had uveitis or iritis (inflammatory conditions of the eye).

3. What if I am taking other medicines?

Tell your doctor or pharmacist 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 SUN can interfere with each other. These include:

- medicines that may affect your kidneys such as fluid tablets
- aminoglycoside medicines used to treat severe infections.

You may need to take different amounts of these medicines or you may need to take different medicines.

Your doctor or pharmacist has more information.

4. How do I use Zoledronic Acid SUN?

How much to use

Follow all directions given to you by your doctor, nurse and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, nurse or pharmacist for help before treatment starts.

Make sure you drink enough fluids before and after the treatment with Zoledronic acid SUN as directed by your doctor.

Two glasses of fluid (such as water) before and after the infusion are usually enough. This will help to prevent dehydration.

You may eat normally on the day you are treated with Zoledronic Acid SUN.

How does it work

Zoledronic Acid SUN works by slowing down bone resorption, which allows the bone-forming cells time to rebuild normal bone. This allows bone remodeling to go back to normal and protects the bones from being weakened.

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 reason.

Zoledronic Acid SUN is only available with a doctor's prescription. It is not addictive.

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

How it will be given

Zoledronic Acid SUN will be given to you by infusion into a vein by your doctor or nurse once a year. The infusion will take at least 15 minutes.

How much is given

A 100mL infusion will last at least 15 minutes.

How long treatment will last

For osteoporosis, each dose of Zoledronic Acid SUN lasts one year. Your doctor will check your condition and may prescribe further annual doses.

For Paget's disease, each dose of Zoledronic Acid SUN may work for longer than one year. Your doctor will let you know if you need to be treated again.

If you use too much of this medicine

If you think that you have used too much of this medicine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Tell your doctor if you have any of the following symptoms:

- muscle spasms
- numbness or tingling sensation, especially around the mouth
- shortness of breath.

These symptoms may mean the level of calcium in your blood has fallen too far.

5. WHAT SHOULD I KNOW WHILE USING Zoledronic Acid SUN?

Things you should do

If you get a headache, fever or other flu-like symptoms in the first three days after you are given Zoledronic Acid SUN, take paracetamol if your doctor has told you to.

Some people get short-lasting flu-like symptoms after having Zoledronic Acid SUN. Paracetamol can provide some relief.

Take calcium and vitamin D supplements if your doctor has told you to.

- Most people with osteoporosis do not get enough calcium and vitamin D in their diet and supplements are needed to help strengthen your bones.
- If you are being treated with Zoledronic Acid SUN for Paget's disease, your doctor should advise corrective treatment for a vitamin D deficiency and that you take calcium and vitamin D supplements for at least the first ten days after you have Zoledronic Acid SUN to reduce the risk of low calcium levels in your blood.

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

Your doctor may want you to have X-rays, bone density scans or blood tests from time to time to make sure Zoledronic Acid SUN is working and to prevent unwanted side effects from happening.

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

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 you get while you are being treated with Zoledronic Acid SUN. This may include persistent pain, swelling, loosening of a tooth and/or non-healing sores of the mouth or jaw.

A dental condition called jaw osteonecrosis has been reported, primarily in patients being treated with this type of medicine for other illnesses.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Zoledronic Acid SUN.

Tell any other doctor, dentist or pharmacist who treats you that you are having Zoledronic Acid SUN.

Driving or using machines

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

Zoledronic Acid SUN has no known effect on the ability to drive or use machines but, as a general precaution, if you are travelling home by car after the infusion, arrange to have someone else drive.

Looking after your medicine

It is unlikely you will have to store Zoledronic Acid SUN at home.

If you do have to store it:

- Store the medicine in a cool dry place at room temperature
- Do not store Zoledronic Acid SUN or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep the medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the floor is a good place to store medicines.

When to discard your medicine

Each Zoledronic Acid SUN vial is to be used for one injection only and then discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• short-lasting fever, sometimes with flu-like symptoms, headache, chills, pain or aching in the muscles or joints. Take paracetamol if your doctor has told you to. Paracetamol can provide some relief.• redness, swelling or pain where the needle for the infusion was inserted• upset stomach, abdominal pain, loss of appetite or other eating disorder, thirst or heartburn• nausea, vomiting, diarrhoea, with possible dehydration | Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you. |

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| <ul style="list-style-type: none"> constipation dry mouth, toothache or sore throat lack of energy, tiredness and lack of interest, weakness, dizziness, low blood pressure pain in your back, neck, shoulders, arms, legs or chest muscles, swollen or stiff joints, muscle stiffness, weakness or spasm, tingling or numbness of your hands or feet swollen fingers or lower legs due to fluid build-up swollen, red, painful or itchy eyes or sensitivity of the eyes to light palpitations (feeling of fast, forceful and/or irregular heartbeat), which may be accompanied by dizziness and breathlessness excessive sweating difficulty sleeping. <p>Fracture of thigh bone</p> <p>Weakness or discomfort in your thigh, hip or groin may be early indications of a possible fracture of the thigh bone.</p> <p>Unusual fracture of the thigh bone particularly in patients on long term treatment for osteoporosis may occur.</p> <p>Dental Treatments</p> <p>Pain in the mouth, teeth and jaw, swelling of sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis).</p> | <p>Contact your doctor.</p> <p>Tell your doctor and dentist immediately about any dental symptoms you get after you have Zoledronic Acid SUN.</p> |
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Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> signs of allergy such as rash, itching or hives on the skin; swelling of the face, throat, lips, tongue or other part of the body; shortness of breath, difficulty breathing or swallowing; tightness of the chest | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p> |

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| <ul style="list-style-type: none"> signs that the level of calcium in your blood may have fallen too far, such as muscle spasms, numbness or tingling sensation, especially around the mouth, shortness of breath signs that the level of phosphorus in your blood may have fallen too far, such as muscle problems and weakness, confusion, irritation and delirium signs that your kidneys may not be working properly, such as decreased urine output. <p>The above side effects may be serious. You may need urgent medical attention.</p> | <p>these serious side effects.</p> |
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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.

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

7. Product details

What Zoledronic Acid SUN contains

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| Active ingredient (main ingredient) | Zoledronic Acid |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> mannitol sodium citrate water for injections. |

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

What Zoledronic Acid SUN looks like

Zoledronic Acid SUN solution for injection is supplied in a transparent glass vial containing 100mL of a clear, colourless solution. Zoledronic Acid SUN is supplied as packs containing one vial. The vial stopper is not made with natural rubber latex or dry natural rubber. AUST R 208101.

Who distributes Zoledronic Acid SUN

Sun Pharma ANZ Pty Ltd
Suite 2.02, Level 2

12 Waterloo Road
Macquarie Park NSW 2113
Australia
Email: customerservice.aus@sunpharma.com
Tel: 1800 726 229

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