

XGEVA®

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 Xgeva?

Xgeva is used to prevent serious bone complications in adults with multiple myeloma or in adults with bone metastasis caused by solid tumour cancer; to treat giant cell tumour of bone which cannot be treated by surgery, where surgery is not the best option, or which has returned after treatment in adults or adolescents whose bones have stopped growing; or to reduce high levels of calcium in the blood in cancer patients if bisphosphonates do not work.

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

2. What should I know before I use Xgeva?

Do not use if you have ever had an allergic reaction to denosumab or any of the ingredients listed at the end of the CMI.

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

Tell your doctor if you have calcium deficiency.

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

3. What if I am taking other medicines?

Some medicines may interfere with Xgeva and affect how it works.

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 Xgeva?

The recommended dose of Xgeva is 120 mg administered once every 4 weeks, as a single injection under the skin (subcutaneous).

More instructions can be found in Section [4. How do I use Xgeva?](#) in the full CMI.

5. What should I know while using Xgeva?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, nurse or
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	<p>pharmacist you visit that you are using Xgeva.</p> <ul style="list-style-type: none"> ● Take calcium and vitamin D supplements if your doctor has told you to. ● Maintain good oral hygiene when being treated with Xgeva. ● Attend all of your treatment and doctor's appointments so that your progress can be checked. ● Tell your doctor immediately if you become pregnant while taking Xgeva or within 5 months of your last dose.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine without checking with your doctor.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Store Xgeva in the refrigerator (2°C to 8°C). Do not freeze. ● Keep Xgeva in the original pack to protect your medicine from light.

For more information, see Section [5. What should I know during treatment with Xgeva?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction; muscle spasms, twitches or cramps, numbness or tingling in your fingers, toes or around your mouth; persistent pain or swelling and/or non-healing sores in your mouth or jaw; pain in your hip, groin, or thigh, which is sometimes severe; swollen, red area of skin that feels hot and tender (cellulitis) and sometimes experienced with fever and chills.

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.

XGEVA®

Active ingredient(s): *Denosumab* (den"-os"-u"-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Xgeva. **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 Xgeva.**

Where to find information in this leaflet:

- [1. Why am I using Xgeva?](#)
- [2. What should I know before I use Xgeva?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Xgeva?](#)
- [5. What should I know during treatment with Xgeva?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Xgeva?

Xgeva contains the active ingredient denosumab. Denosumab is a protein (monoclonal antibody) that attaches (binds) specifically to another unique protein in the body in order to slow down bone destruction caused by cancer spreading to the bone (bone metastasis or bone lesions) or by giant cell tumour of bone. Xgeva reduces the amount of calcium in blood by reducing the

breakdown of bones. In patients with hypercalcaemia of malignancy, the breakdown of bones can cause too much calcium in the blood.

Xgeva is used:

- to prevent serious complications in adults with multiple myeloma. Multiple myeloma is a cancer of plasma cells (a type of white blood cell).
- to prevent serious bone complications caused by bone metastasis or bone lesions, such as fracture, pressure on the spinal cord or the need to receive radiation therapy or surgery.
- to treat giant cell tumour of bone which cannot be treated by surgery, where surgery is not the best option, or which has returned after treatment, in adults or adolescents whose bones have stopped growing.
- to reduce high levels of calcium in the blood in cancer patients (hypercalcaemia of malignancy) after other drugs called bisphosphonates did not work.

Xgeva contains the same medicines as Prolia[®], which is used to treat osteoporosis. Xgeva, which is given at a higher dose once every 4 weeks, should not be used to treat osteoporosis.

Your doctor, however, may prescribe Xgeva for another purpose.

2. What should I know before I use Xgeva?

Warnings

Do not use Xgeva if:

- you are allergic to denosumab, any of the ingredients listed at the end of this leaflet, or any medicines that are produced using Chinese Hamster Ovary cells.
- you have a very low level of calcium in your blood which has not been treated.
- you are a child or adolescent under 18 years of age except for adolescents with giant cell tumour of the bone whose bones have stopped growing.
- you have wounds or sores in your mouth from dental or oral (mouth) surgery that has not yet healed.
- you are pregnant. There is no information on use of this medicine during pregnancy.
- the packaging is torn or shows signs of tampering.
- the Xgeva solution is cloudy or discoloured.

Check with your doctor if you:

- are taking medicines to treat osteoporosis.
- have allergies to any other medicines, or any other substances such as foods, preservatives or dyes.
- have been told by a doctor or healthcare professional that you have an intolerance to some sugars, since Xgeva contains sorbitol (E420).

- have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Xgeva pre-filled syringe contains phenylalanine . Xgeva solution in each single-use vial does not contain phenylalanine. Patients with PKU should be administered Xgeva from the single-use vial containing 120 mg in 1.7 mL solution.
- have calcium deficiency. Your doctor may do a blood test to check your calcium levels before you use Xgeva.
- are unable to take daily calcium or vitamin D supplements.
- have or have had severe kidney problems, kidney failure or have needed dialysis, which may increase your chance of getting low blood calcium, especially if you do not take calcium supplements.
- have been told by a doctor or healthcare professional that you are a patient who is still growing. Some patients with giant cell tumour of the bone and some patients who are still growing during treatment with XGEVA have developed high calcium levels in the blood weeks to months after stopping treatment. Your doctor will monitor you for signs and symptoms of high levels of calcium after you stop XGEVA treatment.
- had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw, a "heavy jaw feeling" or loosening of a tooth. Severe jaw bone problems may happen when you take Xgeva. Patients undergoing chemotherapy or taking steroids, who do not receive routine dental care or have gum disease, may have a higher risk of developing jaw problems. Your doctor

may recommend a dental examination before you start treatment with Xgeva.

- take any medicines for any other condition.

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

Do not use Xgeva if you are pregnant. There is no information on use of this medicine during pregnancy. Tell your doctor if you become pregnant during treatment with Xgeva or within 5 months of your last dose.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed while you are undergoing treatment with Xgeva. It is not known if the active ingredient in Xgeva passes into breast milk.

Use in Children

Do not use Xgeva in children or adolescents under 18 years of age except for adolescents with giant cell tumour of the bone whose bones have stopped growing. The use of Xgeva has not been studied in children and adolescents with other cancers that have spread to bone.

3. What if I am taking other medicines?

Tell your doctor, nurse 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.

Tell your doctor if you are taking another medicine containing denosumab. Xgeva should not be taken together with other medicines containing denosumab (such as Prolia) or with other medicines used to treat osteoporosis, unless directed by your doctor.

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

4. How do I use Xgeva?

How is Xgeva given

- Xgeva is given as an injection under the skin into your thigh, abdomen or upper arm. This is called a subcutaneous injection.
- Xgeva should be given under the responsibility of a healthcare professional.
- You can inject the Xgeva pre-filled syringe in your thigh or abdomen (except 5 cm (2 inches) around your belly button). The first self-administration with the XGEVA pre-filled syringe should be supervised by a healthcare professional. Someone else can inject XGEVA into your thigh, abdomen, or outer area of the

upper arm. You or your caregiver should be trained in injection techniques by a healthcare professional.

If you are under the age of 18, Xgeva should be administered by a healthcare professional or trained caregiver.

How much Xgeva will I be given

- For each dose, you will be given 120 mg as a single injection.

When will you be given Xgeva

- Xgeva is injected once every 4 weeks.
- If you are being treated for giant cell tumour of bone or high blood levels of calcium caused by cancer (hypercalcaemia of malignancy), you will receive an additional dose 1 week and 2 weeks after the first dose.
- Continue using Xgeva for as long as your doctor tells you.
- You should also take calcium and vitamin D supplements while using Xgeva. Your doctor, nurse or pharmacist will discuss this with you.

If you miss a dose of Xgeva

If you miss a dose, Xgeva should be administered as soon as possible. From then on, Xgeva should be scheduled every 4 weeks from the date of the last injection.

If you use too much Xgeva

If you think you or anyone else has received too much Xgeva 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.

5. What should I know during treatment with Xgeva?

Things you should do

- Tell your dentist or doctor that you are being treated with Xgeva if you are undergoing dental treatment or will undergo dental surgery.
- Remind any doctor, dentist, nurse or pharmacist you visit that you are using Xgeva.
- You should take calcium and vitamin D supplements while being treated with XGEVA unless your blood calcium is high. Your doctor will discuss this with you. If the level of calcium in your blood is low, your doctor may decide to give you calcium supplements before you start treatment with XGEVA.
- Maintain good oral hygiene when being treated with Xgeva.

Your routine dental hygiene should include brushing your teeth and tongue after every meal, including the evening and gentle flossing once a day to remove plaque.

Use a mirror and check your teeth and gums regularly for any changes such as sores or bleeding gums. If you notice any problems, tell your doctor and dentist immediately.

- Attend all of your doctor's appointments so that your progress can be checked. Your doctor may recommend you have some blood or urine tests, X-rays or bone scans from time to time to ensure the medicine is working.

Call your doctor straight away if you:

- have spasms, twitches, or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth. You may have low levels of calcium in your blood.
- have any dental symptoms including pain and/or non-healing sores, or unusual feeling in your teeth or gums, or any dental infections. Some people have experienced severe jaw bone problems while being treated with Xgeva.
- develop a swollen, red area of skin that feels hot and tender (cellulitis) and sometimes experienced with fever and chills.
- experience new or unusual pain in your hip, groin, or thigh. Some people have developed unusual fractures in their thigh bone while being treated with Xgeva.

- become pregnant while taking Xgeva.

Things you should not do

- Do not stop using this medicine without checking with your doctor.

After your treatment with Xgeva is stopped, there may be an increased risk of broken bones in your spine, especially if you have a history of broken bones or have had osteoporosis (a condition in which bones become thin and fragile).

Some patients with giant cell tumor of the bone and some who are still growing during treatment with Xgeva, have developed high calcium levels in the blood weeks to months after stopping treatment. Your doctor will monitor you for signs and symptoms of high levels of calcium, after you stop using Xgeva.

- Do not use Xgeva to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Xgeva affects you.

Xgeva has no known effects on the ability to drive or use machines, but as a general precaution, avoid driving soon after you have an injection. Arrange to have someone else drive.

Looking after your medicine

If you need to store your Xgeva before use, follow the instructions in the carton on how to take care of your medicine properly.

- Store Xgeva in the refrigerator (between 2 and 8°C). Do not freeze.
- Keep your medicine in the original carton to protect from light.
- Your medicine may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable.
- Once your medicine has been left to reach room temperature (up to 25°C), do not put it back in the refrigerator and it must be used within 30 days.
- Do not shake or vigorously agitate the vial or pre-filled syringe.

Keep it where young children cannot reach it.

When to discard your medicine

Xgeva is for single use in one patient only. Dispose any unused or expired medicine as instructed below.

Getting rid of any unwanted medicine

Your doctor or nurse is likely to dispose of Xgeva for you. However, if you need to get rid of this medicine because you no longer need to use it, 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 about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut and digestion:</p> <ul style="list-style-type: none">• nausea• diarrhoea• constipation• vomiting• abdominal pain• decreased appetite <p>Lungs and upper airway:</p> <ul style="list-style-type: none">• shortness of breath while exercising• cough <p>Muscle and skeleton:</p> <ul style="list-style-type: none">• back pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● bone, joint, and/or muscle pain <p>Skin and hair:</p> <ul style="list-style-type: none"> ● unusual hair loss or thinning ● rash 	

Less serious side effects continued

Less serious side effects continued	What to do
<p>Ears:</p> <ul style="list-style-type: none"> ● ear pain, discharge from the ear and/or an ear infection. These could be signs of bone damage in the ear <p>Brain and nerves:</p> <ul style="list-style-type: none"> ● headache ● difficulty sleeping <p>General:</p> <ul style="list-style-type: none"> ● low level of red blood cells ● feeling tired and/or weak ● weight loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects continued	What to do
<ul style="list-style-type: none"> • pain at the injection site. 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • 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. <p>Signs of calcium deficiency:</p> <ul style="list-style-type: none"> • muscle spasms, twitches or cramps • numbness or tingling in your fingers, toes or around your mouth <p>Signs of problems with your mouth, teeth or jaw:</p>	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● persistent pain or swelling and/or non-healing sores in your mouth or jaw ● loose teeth <p>Patients undergoing chemotherapy, taking steroids, or having a dental procedure, who do not receive routine dental care or have gum disease, may have a higher risk of developing jaw problems.</p> <p>Signs of bone fractures:</p> <ul style="list-style-type: none"> ● bone, joint and/or muscle pain, including pain in your hip, groin, or thigh, which is sometimes severe 	

Serious side effects continued

Serious side effects continued	What to do
<p>Signs of skin infection:</p> <ul style="list-style-type: none"> ● develop a swollen, red area of skin that feels hot and tender (cellulitis) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your</p>

Serious side effects continued	What to do
and sometimes experienced with fever and chills	nearest hospital if you notice any of these serious side effects.

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.

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.

What Xgeva contains

Active ingredient (main ingredient)	denosumab
Other ingredients (inactive ingredients)	glacial acetic acid polysorbate 20 phenylalanine (in pre-filled syringe only) sodium hydroxide sorbitol water for injections

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

What Xgeva looks like

Xgeva is a clear, colourless to slightly yellow solution for injection. It may contain trace amounts of clear to white particles.

Xgeva comes in two formulations:

A pack of one single-use vial containing 120 mg of denosumab (70 mg/1.0 mL). Aust R 175041.

A pack of one single-use pre-filled syringe with automatic needle guard containing 120 mg of denosumab (120mg/1.0 mL). Aust R 438913.

Who is the sponsor

Amgen Australia Pty Ltd

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