

XGEVA®

Denosumab(rch) - den"-os"-u"-mab

Consumer Medicine Information (CMI)

What is in this CMI

What is in this CMI

What Xgeva is used for

Before you are given it

When you must not be given it

Before you are given it

Taking other medicines

How it is given

Instructions for injecting Xgeva

How much is given

When to use it

How long to use it

If you miss a dose

If you are given too much (overdose)

While you are using it

Things you must do

Things you must not do

Things to be careful of

Side effects

Storing Xgeva

After using it

Disposal

Product description

What it looks like

Ingredients

Sponsor

This leaflet answers some common questions about Xgeva.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine

against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Xgeva is used for

Xgeva contains the active substance denosumab, which 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 medicine as Prolia®, which is used to treat osteoporosis in women after menopause. 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription. It is not addictive.

Before you are given it

When you must not be given it

Do not use Xgeva if you have an allergy to:

- any medicine containing denosumab
- any of the ingredients listed at the end of this leaflet
- any medicines that are produced using Chinese Hamster Ovary cells.

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.

Your healthcare professional will not administer Xgeva to you if you have a very low level of calcium in your blood which has not been treated.

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.

Talk to your doctor before breast-feeding while you are undergoing treatment with Xgeva.

It is not known if the active ingredient, denosumab, passes into breast milk.

Do not use Xgeva if you have wounds or sores in your mouth from dental or oral (mouth) surgery that have not yet healed.

Do not use it in a child or adolescent 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.

Do not use it after the expiry date [EXP:] printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

Do not use it if the Xgeva solution is cloudy or discoloured.

There may be some translucent to white particles of protein in the solution, however the medicine can still be used.

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

Before you are given it

Tell your doctor if:

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

Your doctor may do a blood test to check your calcium levels before you use Xgeva.
- **you are unable to take daily calcium or vitamin D supplements.**
- **you 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.**
- **you are pregnant or intend to become pregnant.**

Xgeva is not recommended to be used during pregnancy. Your doctor can discuss with you the potential risks involved.

- **you are breast-feeding or are planning to breast-feed.**

It is not known whether the active ingredient, denosumab, passes into breast milk.

- **you 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.

- **you 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.

If you have not told your doctor about any of the above, tell him/her before you start using Xgeva.

Taking other medicines

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

How it is given

Xgeva is given as an injection under the skin. This is called a subcutaneous injection.

Instructions for injecting Xgeva

Xgeva is supplied in a vial. Your doctor or nurse will give you the injection.

How much is given

The dose is 120 mg administered once every 4 weeks, as a single injection under the skin.

Xgeva will be injected into your thigh, abdomen or upper arm. 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.

You should also take calcium and vitamin D supplements while receiving Xgeva. Your doctor, nurse or pharmacist will discuss this with you.

When to use it

Xgeva is injected once every 4 weeks.

How long to use it

Continue using Xgeva for as long as your doctor tells you.

If you miss a dose

If you miss a dose, it should be administered as soon as possible.

From then on, it should be scheduled every 4 weeks from the date of the last injection.

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126) if you think you or anyone else may have had too much Xgeva.

Do this even if there are no signs of discomfort or poisoning.

While you are using it

Things you must do

Tell any other doctor, nurses and pharmacist who treat you that you are having this medicine.

If you are about to be started on any other medicine, remind your doctor, nurse or pharmacist that you are being treated with Xgeva.

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

Most people do not get enough calcium and vitamin D in their diet and supplements are needed.

Tell your doctor immediately 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.

Severe jaw bone problems may happen when you take Xgeva. Tell your doctor and dentist immediately about any dental symptoms including pain and/or non-healing sores, or unusual feeling in your teeth or gums, or any dental infections.

Tell your dentist or doctor that you are being treated with Xgeva if you are under dental treatment or will undergo dental surgery.

Maintain good oral hygiene when being treated with Xgeva.

Tell your doctor immediately if you develop a swollen, red area of skin that feels hot and tender (cellulitis) and sometimes experienced with fever and chills while being treated with Xgeva.

Contact your doctor if you 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.

If you become pregnant while using this medicine, tell your doctor immediately.

Your doctor can discuss with you the risks of having it while you are pregnant.

Contact your doctor if you plan to stop taking Xgeva.

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).

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.

Things you must not do

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.

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

Things to be careful of

Be careful driving or using machinery until you know how it 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.

Practice good dental hygiene. Your routine dental hygiene should include:

- Brushing your teeth and tongue after every meal, including the evening
- 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.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after using Xgeva.

All medicines can have some unwanted side effects. Sometimes they are serious but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

If any of the following happen tell your doctor, nurse or pharmacist immediately or go to the Emergency at your nearest hospital:

- 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.

These are very serious side effects. If you experience them, you may be having a serious allergic reaction to the medicine. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- muscle spasms, twitches or cramps, numbness or tingling in your fingers, toes or around your mouth
- bone, joint and/or muscle pain, which is sometimes severe
- persistent pain and/or non-healing sores in your mouth or jaw

These may be serious side effects. You may need urgent medical attention. These side effects are common or very common

Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following and they worry you:

- Nausea
- Low level of red blood cells
- Feeling tired
- Back pain

These are mild common side effects of the medicine.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storing Xgeva

If you need to store your Xgeva before use:

- **Keep your medicine in the refrigerator, between 2°C and 8°C. Do not freeze.**

Keep your medicine in the carton in order to protect it from light. If you remove the medicine from the carton it will not keep well.

- **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), it must be used within 30 days.

Do not shake or vigorously agitate the vial.

- **Keep it where children cannot reach it.**

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

After using it

Disposal

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

Xgeva is a clear, colourless to slightly yellow solution for injection

supplied in a vial. It may contain trace amounts of clear to white particles.

Xgeva comes in a pack of one single-use vial containing 120 mg of denosumab (70 mg/1.0 mL).

Ingredients

Active ingredient: denosumab.

Inactive ingredients:

- Acetate
- sodium hydroxide
- sorbitol
- Water for Injections.

This medicine does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Xgeva is supplied in Australia by:

Amgen Australia Pty Ltd
(ABN 31 051 057 428)

Level 7, 123 Epping Road
North Ryde NSW 2113

Medical Information: 1800 803 638

This CMI was prepared in July 2018.

Australian Registration Number:

AUST R 175041

Xgeva® is a registered trademark of Amgen.