Package leaflet: Information for the patient

XGEVA 120 mg solution for injection in pre-filled syringe
denosumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Your doctor will give you a patient reminder card, which contains important safety information you need to be aware of before and during your treatment with XGEVA.

What is in this leaflet

1. What XGEVA is and what it is used for
2. What you need to know before you use XGEVA
3. How to use XGEVA
4. Possible side effects
5. How to store XGEVA
6. Contents of the pack and other information

1. What XGEVA is and what it is used for

XGEVA contains denosumab, a protein (monoclonal antibody) that works to slow down bone destruction caused by cancer spreading to the bone (bone metastasis) or by giant cell tumour of bone.

XGEVA is used in adults with advanced cancer to prevent serious complications caused by bone metastasis (e.g. fracture, pressure on the spinal cord or the need to receive radiation therapy or surgery).

XGEVA is also used to treat giant cell tumour of bone, which cannot be treated by surgery or where surgery is not the best option, in adults and adolescents whose bones have stopped growing.

2. What you need to know before you use XGEVA

Do not use XGEVA:

- if you are allergic to denosumab or any of the other ingredients of this medicine (listed in section 6).

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.

Your healthcare professional will not administer XGEVA to you if you have unhealed wounds from dental or oral surgery.

Warnings and precautions

Talk to your doctor before using XGEVA.

Calcium and vitamin D supplementation
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.

Low calcium levels in the blood
Please 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 and/or seizures, confusion or loss of consciousness while being treated with XGEVA. You may have low levels of calcium in your blood.

Renal impairment
Tell your doctor if you have or have had severe kidney problems, kidney failure or have needed dialysis, which may increase your risk of getting low blood calcium, especially if you do not take calcium supplements.

Problems with your mouth, teeth or jaw
A side effect called osteonecrosis of the jaw (bone damage in the jaw) has been reported commonly (may affect up to 1 in 10 people) in patients receiving XGEVA injections for cancer-related conditions. Osteonecrosis of the jaw can also occur after stopping treatment.

It is important to try to prevent osteonecrosis of the jaw developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing osteonecrosis of the jaw, there are some precautions you should take:

- Before receiving treatment, tell your doctor/nurse (healthcare professional) if you have any problems with your mouth or teeth. Your doctor should delay the start of your treatment if you have unhealed wounds in your mouth from dental procedures or oral surgery. Your doctor may recommend a dental examination before you start treatment with XGEVA.
- While being treated, you should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with XGEVA.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Patients undergoing chemotherapy and/or radiotherapy, taking steroids or anti-angiogenic medicines (used to treat cancer), undergoing dental surgery, who do not receive routine dental care, have gum disease or who are smokers, may have a higher risk of developing osteonecrosis of the jaw.

Unusual thigh bone fractures
Some people have developed unusual fractures in their thigh bone while being treated with XGEVA. Contact your doctor if you experience new or unusual pain in your hip, groin, or thigh.

High calcium levels in the blood after stopping treatment with XGEVA
Some patients with giant cell tumour of the bone 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 receiving XGEVA.

Children and adolescents

XGEVA is not recommended for children and 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.

Other medicines and XGEVA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription. It is especially important that you tell your doctor if you are being treated with

- another medicine containing denosumab
- a bisphosphonate

You should not take XGEVA together with other medicines containing denosumab or bisphosphonates.

Pregnancy and breast-feeding

XGEVA has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant, or plan to get pregnant. XGEVA is not recommended for use if you are pregnant. Women of child-bearing potential should use effective methods of contraception while being treated with XGEVA and for at least 5 months after stopping treatment with XGEVA.

If you become pregnant during treatment with XGEVA or less than 5 months after stopping treatment with XGEVA, please inform your doctor.

It is not known whether XGEVA is excreted in breast milk. It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or whether to stop taking XGEVA, considering the benefit of breast-feeding to the baby and the benefit of XGEVA to the mother.

If you are nursing during treatment with XGEVA, please inform your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

XGEVA has no or negligible influence on the ability to drive and use machines.

XGEVA contains sorbitol

This medicine contains 37 mg sorbitol in each pre-filled syringe.

XGEVA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 120 mg dose, that is to say essentially ‘sodium-free’.

XGEVA contains polysorbate

This medicine contains 0.1 mg of polysorbate 20 in each 1.0 mL PFS solution. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

XGEVA pre-filled syringe contains phenylalanine

This medicine contains 6.1 mg of phenylalanine in each pre-filled syringe.

Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to use XGEVA

For instructions on how to inject XGEVA, please read the section at the end of this leaflet.

The recommended dose of XGEVA is 120 mg administered once every 4 weeks, as a single injection under the skin (subcutaneous). You can inject the XGEVA pre-filled syringe in your thigh or belly (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. If someone else gives you the injection, XGEVA can be injected into your thigh, belly, or outer area of the upper arm. You or your caregiver should be trained in injection techniques by a healthcare professional. If you are being treated for giant cell tumour of bone, you will receive an additional dose 1 week and 2 weeks after the first dose.

Do not shake.

You should also take calcium and vitamin D supplements while being treated with XGEVA unless you have an excess of calcium in the blood. Your doctor will discuss this with you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor immediately if you develop any of these symptoms while being treated with XGEVA (may affect more than 1 in 10 people):
- spasms, twitches, cramps in your muscles, numbness or tingling in your fingers, toes or around your mouth and/or seizures, confusion or loss of consciousness. These could be signs that you have low calcium levels in the blood. Low calcium in the blood may also lead to a change in heart rhythm called QT prolongation, which is seen by electrocardiogram (ECG).

Please tell your doctor and dentist immediately if you experience any of these symptoms while being treated with XGEVA or after stopping treatment (may affect up to 1 in 10 people):
- persistent pain in the mouth and/or jaw, and/or swelling or non-healing of sores in the mouth or jaw, discharge, numbness or feeling of heaviness in the jaw, or loosening of a tooth could be signs of bone damage in the jaw (osteonecrosis).

Very common side effects (may affect more than 1 in 10 people):
- bone, joint, and/or muscle pain which is sometimes severe,
- shortness of breath,
- diarrhoea.

Common side effects (may affect up to 1 in 10 people):
- low phosphate levels in the blood (hypophosphataemia),
- removal of a tooth,
- excessive sweating,
- in patients with advanced cancer: development of another form of cancer.

Uncommon side effects (may affect up to 1 in 100 people):
- high calcium levels in the blood (hypercalcaemia) after stopping treatment in patients with giant cell tumour of the bone,

- new or unusual pain in your hip, groin or thigh (this may be an early indication of a possible fracture of the thigh bone),
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions),
- injection site reactions including pain around the site where the injection was given.

Rare side effects (may affect up to 1 in 1,000 people):
- allergic reactions (e.g. wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin). In rare cases allergic reactions may be severe.

Not known (frequency cannot be estimated from the available data):
- Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store XGEVA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Keep the pre-filled syringe in the outer carton in order to protect from light.

The pre-filled syringe may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable. Once the pre-filled syringe 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What XGEVA contains

- The active substance is denosumab. Each pre-filled syringe contains 120 mg of denosumab in 1 mL of solution (corresponding to 120 mg/mL).
- The other ingredients are acetic acid, glacial, sodium hydroxide, sorbitol (E420), L-phenylalanine, polysorbate 20 and water for injections.

What XGEVA looks like and contents of the pack

XGEVA is a solution for injection (injection).

XGEVA is a clear, colourless to slightly yellow solution. It may contain trace amounts of translucent to white proteinaceous particles.

Each pack contains one, three or four single use pre-filled syringes with needle guards.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Amgen Limited,
216 Cambridge Science Park,
Milton Road,
Cambridge,
CB4 0WA,
United Kingdom

Manufacturer
Amgen Technology (Ireland) Unlimited Company
Pottery Road
Dun Laoghaire
Co Dublin
Ireland

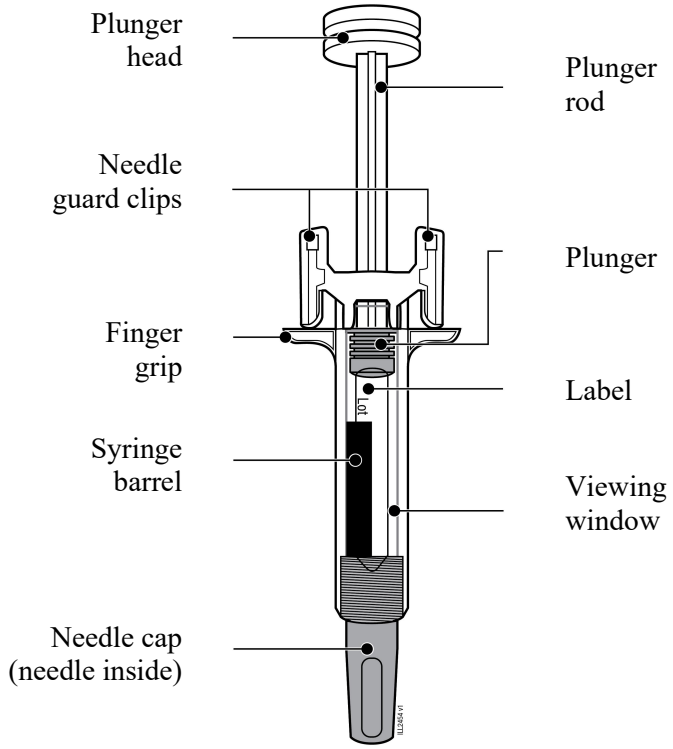
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Amgen Limited
Tel: +44 (0)1223 420305

This leaflet was last revised in February 2026.

Instructions for Use

Getting to know your pre-filled syringe with Automatic Needle Guard



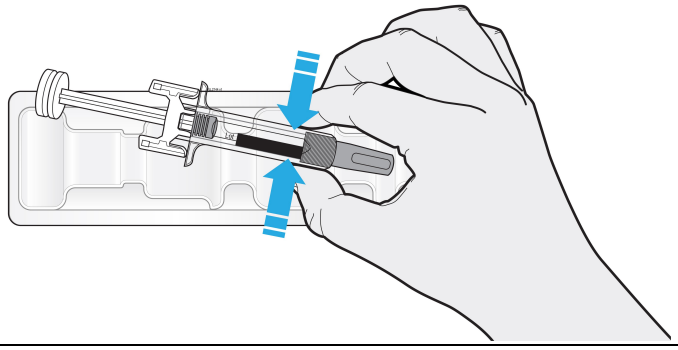
1 Important information you need to know before injecting XGEVA

Using your XGEVA pre-filled syringe:

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- XGEVA is given as an injection into the tissue just under the skin (subcutaneous injection).
- **Do not** use the pre-filled syringe if the carton is damaged or the seal is broken.
- **Do not** shake the pre-filled syringe.
- **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Part of the pre-filled syringe may be broken even if you cannot see the break. If available, use a new pre-filled syringe and call your doctor or healthcare provider.

Important: Keep the pre-filled syringe and sharps disposal container out of the sight and reach of children.

2	**Preparing to inject XGEVA**
2a	**Grasp the pre-filled syringe by the barrel and remove from the tray.**



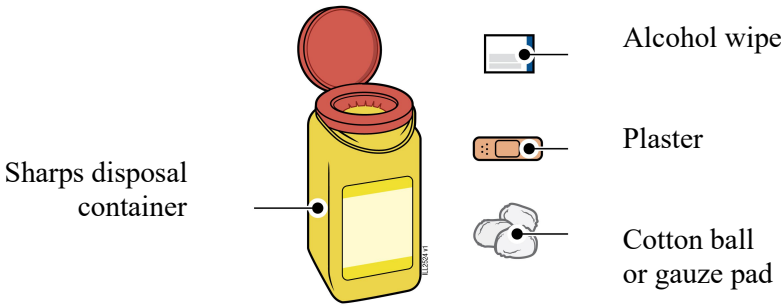
- **Do not** grab the plunger rod, finger grip or the needle cap.
- **Do not** grab the needle guard clips.
- Put any unused pre-filled syringes back into the refrigerator.

2b	**Wait 30 minutes for the pre-filled syringe to reach room temperature.**

WAIT
30
minutes

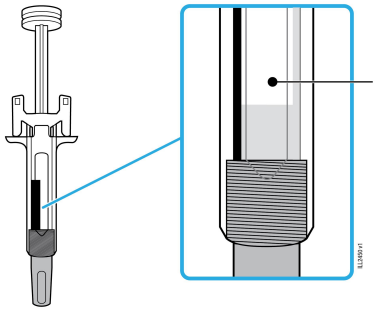
- Let the pre-filled syringe warm up naturally.
- **Do not** heat with hot water, a microwave or direct sunlight.
- **Do not** shake the pre-filled syringe at any time.
- Using the pre-filled syringe at room temperature allows for a more comfortable injection.
- Once the pre-filled syringe has been left to reach room temperature, do not put it back in the refrigerator and it must be used within 30 days.

2c	**Gather and place the items for your injection on a clean, well-lit surface.**



- XGEVA pre-filled syringe (room temperature)
- Sharps disposal container
- Alcohol wipe
- Plaster
- Cotton ball or gauze pad

3	**Getting ready for your injection**
3a	**Inspect the medicine.**

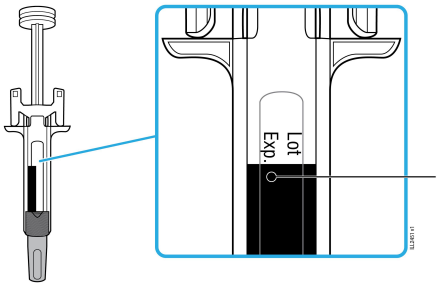


Medicine

- It should be clear, colourless to slightly yellow.
- It may contain trace amounts of translucent to white proteinaceous particles.
- It is okay to see air bubbles in the pre-filled syringe.
- **Do not** use if the medicine is cloudy or discoloured or if it contains many particles or foreign particulate matter.

Important: If the medicine is cloudy, discoloured, or has particles, call your doctor or healthcare provider.

3b	**Check the expiry date (EXP) and inspect the pre-filled syringe.**

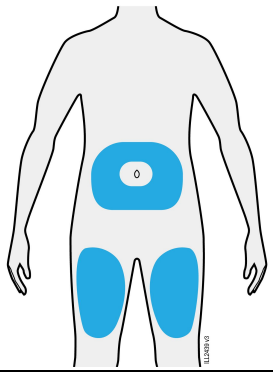


Expiry date

- **Do not** use if the expiry date has passed.
- **Do not** use the pre-filled syringe if:
  - The needle cap is missing or loose.
  - It has cracks or broken parts.
  - It has been dropped on a hard surface.

Important: In all cases, call your doctor or healthcare provider.

3c	**Inject in one of these locations.**



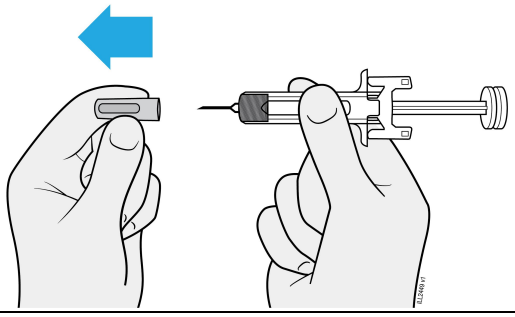
- Inject in your thigh or belly (except 5 cm (2 inches) around your belly button).
- Someone else can inject in your thigh, belly or outer area of the upper arm.
- Wash your hands thoroughly with soap and water.
- Clean injection site with an alcohol wipe.
- Let your skin dry on its own.
- **Do not** touch this area again before injecting.

Important: Avoid areas with scars, stretch marks, or where skin is tender, bruised, red or hard.

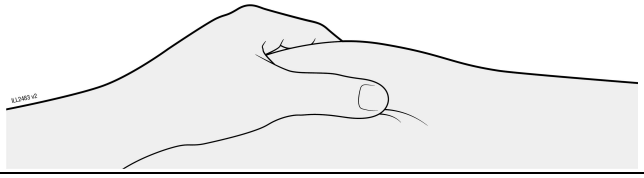
4	**Injecting XGEVA**

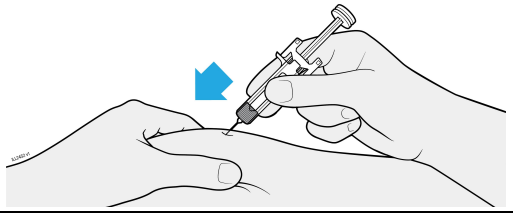
Important: Only remove the needle cap when you can inject right away (within 5 minutes) as this can dry out the medicine.

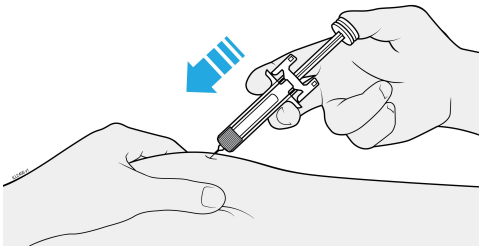
4a	**Pull the needle cap straight off while holding the pre-filled syringe barrel.**



- **Do not** twist or bend the needle cap.
- **Never** put the needle cap back on. It may damage the needle.
- **Do not** let anything touch the needle once the needle cap is removed.
- **Do not** place the uncapped pre-filled syringe on any surface once the needle cap is removed.
- **Do not** try to push air bubbles out of the pre-filled syringe. It is okay to see air bubbles.
- A drop of medicine is normal.

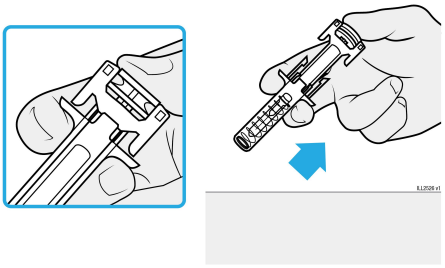
4b	**Pinch the skin around the injection site before the injection.**
PINCH	
	
• Pinch the skin between thumb and index finger to create a bump for the injection. • If possible, the bump should be about 5 cm (2 inches) wide.	

4c	**Insert the needle into the pinched skin.**
INSERT	
	
• Insert the needle into the pinched skin either straight in or at a 45 degree angle. • **Do not** place your finger on the plunger rod while inserting the needle, as this may result in loss of medicine.	

4d	**Slowly press the plunger head down until it is completely between the needle guard clips. You may feel or hear a "snap".**
INJECT	
	
• **Do not** pull back on the plunger at any time. • **Do not** remove the needle until all the medicine is delivered.	

4e	**Keep pressure on the plunger head and remove the needle from skin.**

LIFT

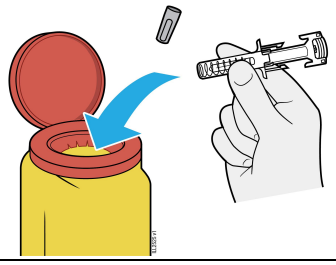


- Keep pressure on the plunger head and take the needle out of the skin.
- Let go of the skin after the needle is removed.
- Slowly take your thumb off the plunger head. This will let the empty pre-filled syringe move up until the entire needle is entirely covered by the needle guard.
- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply a plaster if necessary.

5	**Finishing and disposing XGEVA**

Important: Never put the needle cap back on.

5a	**Discard the used pre-filled syringe and needle cap in the sharps disposal container.**



- Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Do not recycle the pre-filled syringe or throw it into the household waste.

- **Do not** reuse the pre-filled syringe.