

Self-administration of the XGEVA[®] (denosumab) pre-filled syringe

This booklet is for patients who have been prescribed XGEVA[®] (denosumab) pre-filled syringe for the prevention of skeletal-related events caused by bone metastases.

Denosumab is a single subcutaneous injection given once every four weeks.

The 120 mg/1.0 mL pre-filled syringe injection can be administered by a patient or caregiver who has been trained in injection techniques by a healthcare professional.

The first self-administration with the denosumab pre-filled syringe should be supervised by a healthcare professional.

Read all instructions for use thoroughly.



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 the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160. Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily. For a list of side effects please see the Patient Information Leaflet (PIL).

This is a patient material funded by Amgen to support patients with self-administration of the XGEVA[®] (denosumab) pre-filled syringe.

This leaflet is intended for adult patients who have been prescribed denosumab pre-filled syringe and have been specifically trained and advised to self-administer by their healthcare professional.

It is intended to supplement but not replace the guidance of your healthcare professional. Any advice you receive from your advising healthcare professional should supersede this document. For any questions or queries, please contact your advising healthcare professional.

The information in this booklet has been taken from the Patient Information Leaflet. For full information on how denosumab works and the important warnings and precautions for use, including dental requirements and calcium monitoring, you should review the Patient Information Leaflet before taking denosumab.

You can access the Patient Information Leaflet here:

<https://www.medicines.ie/medicines/xgeva-120-mg-solution-for-injection-inpre-filled-syringe-35533/patient-info#tabs>

AMGEN[®]

WHY HAVE I BEEN PRESCRIBED XGEVA®?

Your doctor has prescribed XGEVA® for you to help protect your bones and prevent serious bone complications caused by bone metastases.¹ Many cancers such as breast, prostate, lung and others spread.

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).

Bone metastases — are caused by cancer cells that have spread to the bone from another location. For example, prostate cancer that has spread to the bone is known as metastatic prostate cancer.

WHAT DOES XGEVA® DO?

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

HOW OFTEN WILL I BE GIVEN XGEVA®?

The recommended dose of XGEVA® is 120mg administered once every 4 weeks.¹

WHAT IF I MISS A DOSE?

If you missed a dose, talk to your doctor and healthcare team right away. They will help to get you back on track with your XGEVA® treatment.

WHERE DO I GET XGEVA®?

XGEVA® is dispensed by your community pharmacist.

IMPORTANT INFORMATION YOU NEED TO KNOW:

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

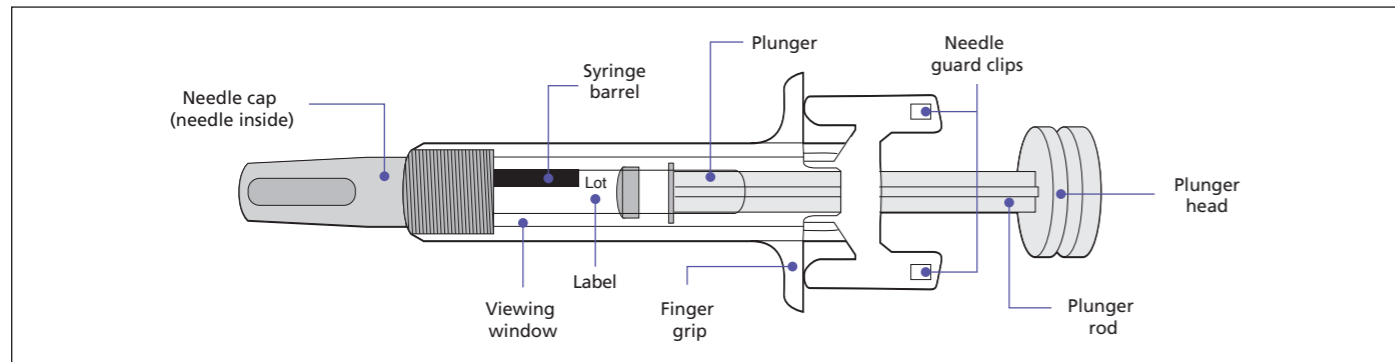
- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider
- Keep the pre-filled syringe in the outer carton in order to protect from light
- Unless your healthcare team advise you otherwise, store the denosumab in a refrigerator (2°C–8°C)
- Do not freeze denosumab
- 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 (up to 25°C), do not put it back in the refrigerator and it must be used within 30 days
- **Do not** use the pre-filled syringe if the carton is damaged or the seal is broken
- **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.
- **Do not** shake the pre-filled syringe
- **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject
- Wash your hands before and after giving the injection
- If possible, try to rotate the injection site for consecutive injections

Please refer to your copy of the denosumab Patient Information Leaflet and Patient Reminder Card for more information.

WHAT YOU NEED TO SELF-ADMINISTER YOUR TREATMENT USING THE PRE-FILLED SYRINGE

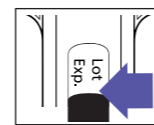
- Denosumab pre-filled syringe (left for 30 minutes to reach room temperature)
- Sharps disposal container
- Alcohol wipe
- Plaster
- Cotton ball or gauze pad
- A clean surface, e.g. table wiped with a clean damp cloth and allowed to dry

GETTING TO KNOW YOUR PRE-FILLED SYRINGE



PREPARING THE INJECTION

Do not use the pre-filled syringe after the expiry date, which is stated on the pre-filled syringe after "EXP". The expiry date refers to the last day of that month.



1 Wash your hands with soap and water and dry them thoroughly. If you are the carer administering denosumab to someone, please ensure to wash your hands thoroughly with soap and water before and after the injection.

2 Remove the pre-filled syringe from the refrigerator. 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.

3 **Wait 30 minutes** for the pre-filled syringe to reach room temperature. Let the pre-filled syringe warm up naturally. **Do not** heat with hot water, a microwave, or direct sunlight, and **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.

4 Sharps disposal container

XGEVA® pre-filled syringe (room temperature)

Alcohol wipe

Plaster

Cotton ball or gauze pad

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

5 Inspect the medicine. It should be clear and 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 solution looks cloudy, 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.

6 Check the expiry date (EXP) and inspect the pre-filled syringe. **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, or it has been dropped on a hard surface. **Important:** In all cases, call your doctor or healthcare provider.

GIVING THE INJECTION

1 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 and **do not** touch this area again before injecting. **Important:** Avoid areas with scars, stretch marks, or where skin is tender, bruised, red, or hard.

2 **Important:** Only remove the needle cap when you can inject right away (within 5 minutes) as this can dry out the medicine. 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 at the end of the needle is normal.

3 **PINCH**

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

4 **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 whilst inserting the needle, as this may result in a loss of medicine.

5 **INJECT**

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

6 **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.

7 **Important:** Never put the needle cap back on. 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.

XGEVA[®] Administration Diary

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It is very important for you to take calcium and vitamin D supplementation daily while receiving XGEVA[®] unless otherwise advised by your doctor

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It is very important for you to take calcium and vitamin D supplementation daily while receiving XGEVA[®] unless otherwise advised by your doctor



CONTACT DETAILS

PLEASE CONTACT YOUR ADVISING HEALTHCARE PROFESSIONAL WITH ANY QUESTIONS OR CONCERNS YOU HAVE.

Contact Details:

REFERENCE:

1. XGEVA® Patient Information Leaflet. Available Online at: <https://www.medicines.ie/medicines/xgeva-120-mg-solution-for-injection-in-pre-filled-syringe-35533/patient-info#tabs> Last Accessed May 2024
2. XGEVA® (denosumab) Summary of Product Characteristics. <https://www.medicines.ie/medicines/xgeva-120-mg-solution-for-injection-in-pre-filled-syringe-35533/spc> Last Accessed May 2024

For a step-by-step video guide on administering denosumab injections using the pre-filled syringe, please visit <https://www.amgencare.ie/xgeva> or scan the QR code:



Amgen Ltd.
21 Northwood Court, Santry, Dublin 9, D09 TX31, Republic of Ireland
www.amgen.co.uk

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