WHAT TO EXPECT WHEN TAKING XGEVA® (DENOSUMAB)

Information for adult patients prescribed XGEVA® (denosumab) for the prevention of serious complications from bone metastasis

AMGEN® care

www.amgencare.ie

MY MEDICAL TEAM

My Specialist

Name:

Hospital/Practice:

Tel. number:

My Nurse

Name:

Hospital/Practice:

Tel. number:

My Dentist

Name:

Practice:

Tel. number:

Please bring this booklet to your hospital, GP, or dentist appointment.

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INTRODUCTION

The aim of this guide is to provide you with further information to help you better understand what to expect during treatment with XGEVA®.

This is in addition to information provided by your healthcare provider, the patient reminder card and the Patient Information Leaflet (PIL) which comes with your medication pack.

The XGEVA® Patient Information Leaflet (PIL) can also be accessed at www.medicines.ie/medicines/xgeva-34257/patient-info

The patient reminder card is included on the last page of this booklet. Should you require another copy, please contact your doctor or Amgen Medical Information on +44 1223 436441, or access it at www.medicines.ie/medicines/xgeva-34257/educational-material-patient

If you have any questions about the benefits or risks of XGEVA®, contact your doctor, nurse or pharmacist.

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.

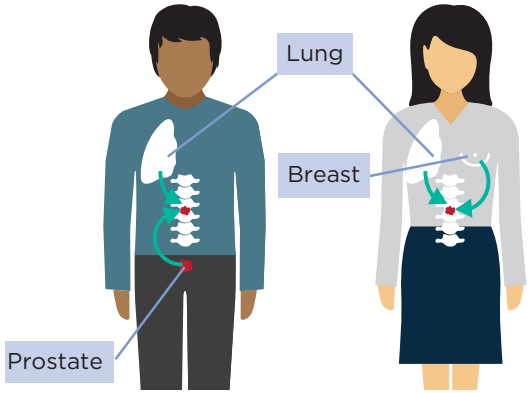
For a list of side effects please see the Patient Information Leaflet (PIL).

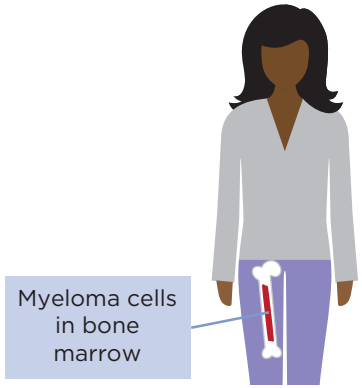
Please note: the Patient Information Leaflet (PIL) or Package Leaflet is the leaflet included in the pack with a medicine.

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 to the bone (bone metastases) which can weaken or damage bones.[2] Also, other types of cancers such as Multiple Myeloma can cause "weak spots" in your bones, called lesions.[3]





Bone metastases - are caused by cancer cells that have spread to the bone from another location.[4] For example, prostate cancer that has spread to the bone is known as metastatic prostate cancer.

Bone lesions - In Multiple Myeloma, blood cells that are made in the bone marrow become cancerous and can build up in the bone to form bone lesions.[5]

As a result of the weakening of your bones, you may be more susceptible to have serious bone complications[1] such as:

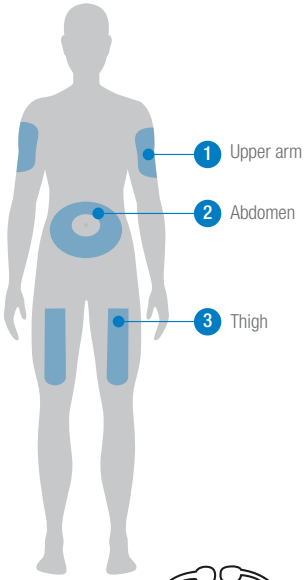
- Broken bones (fractures);
- Pressure on the spinal cord;
- The need to receive radiation therapy or surgery to the bone.

By taking XGEVA® you can help protect your bones and help avoid these kind of events.[1]

WHAT DOES XGEVA® DO?

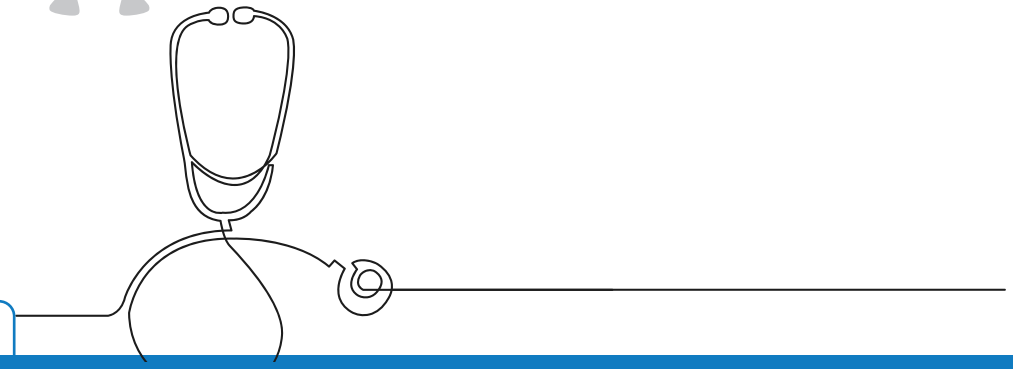
XGEVA® is a protein (monoclonal antibody) that works by slowing down bone destruction.[1] It helps to prevent the weakening of bones and can stop bone problems from occurring.[6] By protecting bone, XGEVA® helps to prevent serious complications caused by bone metastasis (e.g. fracture, pressure on the spinal cord or the need to receive radiation therapy or surgery).[1]

HOW IS XGEVA® GIVEN?



XGEVA® is given as an injection under the skin (subcutaneous injection) into the thigh, abdomen or upper arm.[1]

XGEVA® should be administered under the responsibility of a healthcare professional.[1]



HOW OFTEN WILL I BE GIVEN XGEVA®?

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

WHAT IF I MISS A DOSE?

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

WHERE DO I GET XGEVA® ?

XGEVA® is dispensed by your community pharmacist.

WHAT DO I NEED TO KNOW ABOUT TAKING XGEVA®?

What are the side effects of XGEVA®?[1]

Like all medicines, XGEVA® can cause side effects, although not everybody gets them.

It is important to tell your doctor or nurse about any side effects so they can be monitored and where necessary, treated.

For a FULL LIST OF WARNINGS AND SIDE EFFECTS associated with XGEVA® please refer to the patient information leaflet that is contained inside the carton alongside the vial of XGEVA® or available at www.medicines.ie/medicines/xgeva-34257/patient-info

What important things do I need to know while being treated with XGEVA®?

Pregnancy and breastfeeding[1]

- 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.
- 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.

Calcium and Vitamin D

It is important to take calcium and vitamin D supplements if they are prescribed for you. Calcium helps to strengthen the bones, and vitamin D helps your body to absorb the calcium.[7]

You will be tested to measure the level of calcium in your blood.[6]

Your doctor will not administer XGEVA® to you if you have a very low level of calcium in your blood which has not been treated.[1]

Hypocalcemia occurs when the calcium level of the blood is reduced.[8] This can be caused by the administration of XGEVA® and made worse by other diseases (e.g. poor kidney function).[6]

Symptoms of hypocalcemia include 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 - **contact your doctor straight away if you experience any of these symptoms.[1]**

Tell your doctor if you have or have had severe kidney problems, kidney failure or have needed dialysis.[1]

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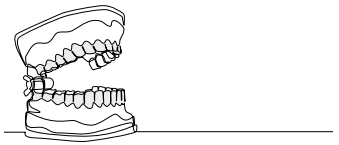


Look after your teeth and gums

A side effect called osteonecrosis of the jaw (ONJ) which is bone damage in the jaw, has been reported commonly (may affect up to 1 in 10 people) in patients receiving XGEVA®. ONJ can also occur after stopping treatment.[1]

It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take[1]:

Before starting treatment:

- **Tell your doctor/nurse 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,** and may recommend a dental examination before you start treatment with XGEVA®.
- 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 ONJ.

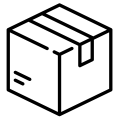
While being treated:

- You should maintain good oral hygiene and receive routine dental checkups. 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 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 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, as these could be signs of ONJ.

☐ Tick (✓) here if you have had your Dental Examination

HOW DO I STORE XGEVA®?[1]

- Store XGEVA® in the refrigerator (between 2°C and 8°C). Do not freeze.
- Keep the medicine in the original carton to protect it from light.



- Your medicine may be left outside the refrigerator to reach room temperature (up to 25°C) before injecting. This will make the injection more comfortable.

- Once your medicine has been left in the carton to reach room temperature (up to 25°C), it must be used within 30 days.
- Do not shake the vial excessively.

For further information on XGEVA®, speak with your healthcare team.

STAY ON TRACK WITH YOUR XGEVA TREATMENT PLAN

- ✓ Track your appointments in the accompanying XGEVA® administration diary
- ✓ Enter your appointments in a diary or smart phone calendar
- ✓ Schedule future appointments in advance
- ✓ Ask family or friends for help getting to your appointment
- ✓ If you are thinking about stopping treatment, speak with your doctor first

HEALTHCARE APPOINTMENTS

DATE	HEALTHCARE PROFESSIONAL	LOCATION	COMMENTS

XGEVA® ADMINISTRATION DIARY

LOT NO.	DATE	XGEVA® INJECTION Please tick and sign confirming XGEVA® injection administered	CALCIUM LEVELS
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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

XGEVA® ADMINISTRATION DIARY

LOT NO.	DATE	XGEVA® INJECTION Please tick and sign confirming XGEVA® injection administered	CALCIUM LEVELS
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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

PATIENT REMINDER CARD

Put this Patient Reminder Card in your wallet, purse or bag so that you have always got it with you while you are taking XGEVA®.

REFERENCES

1. XGEVA® (denosumab), Patient Information Leaflet. [Available at: www.medicines.ie/medicines/xgeva-34257/patient-info]
2. All about Bone Metastases. Oncolink. [Available at: www.oncolink.org/cancers/bone/bone-metastases/all-about-bone-metastases. Last accessed: January 2021]
3. International Myeloma Foundation. Bone Disease. [Available at: https://www.myeloma.org/bone-disease. Last Accessed: January 2021]
4. American Cancer Society. Understanding Advanced and Metastatic Cancer. [Available from: https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/what-is.html. Last Accessed: January 2021]
5. Hameed A et al. Cancer Growth and Metastasis 2014:7 33–42.
6. XGEVA® (denosumab), Summary of Product Characteristics. [Available at: www.medicines.ie/medicines/xgeva-34257/smpc]
7. Calcium/Vitamin D. National Osteoporosis Foundation. [Available at: www.nof.org/patients/treatment/calciumvitamin-d/. Last accessed: January 2021]
8. Hypocalcemia (Low Level of Calcium in the Blood). MSD Manual. [Available at: www.msdmanuals.com/home/hormonal-and-metabolic-disorders/electrolyte-balance/hypocalcemia-low-level-of-calcium-in-the-blood?query=hypocalcemia. Last accessed: January 2021]

INFORMATION TO GIVE TO YOUR DENTIST:

Please tear out this page and give it to your dentist, to inform about your treatment with XGEVA® (denosumab).

Your patient is due to start or is receiving XGEVA® (denosumab) 120mg by subcutaneous injection every 4 weeks

- XGEVA® is indicated for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone[1,2]
- Denosumab is a human monoclonal antibody (IgG2) that targets and binds with high affinity and specificity to RANKL, preventing the RANKL/RANK interaction from occurring and resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction
- Osteonecrosis of the jaw (ONJ) is a condition in which the jawbone becomes necrotic, exposed and does not heal within 8 weeks. The etiology of ONJ is not clear, but may be associated with inhibition of bone remodeling. ONJ has been reported commonly (may affect up to 1 in 10 people) in patients receiving XGEVA®. ONJ can also occur after stopping treatment.

The following risk factors should be considered when evaluating a patient's risk of developing ONJ:

- Potency of the medicinal product that inhibits bone resorption (higher risk for highly potent compounds), route of administration (higher risk for parenteral administration) and cumulative dose of bone resorption therapy
- Cancer, co-morbid conditions (e.g. anaemia, coagulopathies, infection), smoking
- Concomitant therapies: corticosteroids, chemotherapy, angiogenesis inhibitors, radiotherapy to head and neck
- Poor oral hygiene, periodontal disease, poorly fitting dentures, pre-existing dental disease, invasive dental procedures e.g. tooth extractions

(please turn over)

Prior to starting XGEVA®, patients are recommended to have a dental examination

- Prior to starting XGEVA® it is recommended that patients have a dental examination with preventive dentistry and an individual benefit:risk assessment. XGEVA® should not be initiated in patients with unhealed lesions from dental or oral surgery. The start of treatment/new treatment course should be delayed in patients with unhealed open soft tissue lesions in the mouth

For patients receiving XGEVA®, please advise the following

- Please advise your patient to maintain good dental hygiene and receive routine dental check–ups whist taking XGEVA® and ensure their dentures fit properly
- Please advise your patient to report any oral symptoms to you and their doctor immediately - such as dental mobility, pain or swelling, or non-healing of sores or discharge, whilst taking denosumab
- Please inform the patient's Oncology Unit first if any dental treatment, specifically a tooth extraction or any invasive dental procedure needs to be carried out. While on treatment, invasive dental procedures should be performed only after careful consideration and be avoided in close proximity to XGEVA® administration
- The management plan of patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ.

Please visit www.ADEE.org for more information on ONJ

References:

1. XGEVA® (denosumab), Patient Information Leaflet [Available at: www.medicines.ie/medicines/xgeva-34257/patient-info]
2. XGEVA® (denosumab), Summary of Product Characteristics [Available at: www.medicines.ie/medicines/xgeva-34257/smpc]

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FOR FURTHER INFORMATION PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT IS CONTAINED INSIDE THE CARTON ALONGSIDE THE VIAL OF XGEVA® OR AVAILABLE AT www.medicines.ie/medicines/xgeva-34257/patient-info

VISIT THE PATIENT WEBSITE WWW.AMGENCARE.IE FOR MORE INFORMATION (FOR QUICK ACCESS, SCAN THE BELOW QR CODE WITH YOUR PHONE'S CAMERA OR QR READER APP)

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