

Information for
patients prescribed
XGEVA[®] (denosumab)
for the prevention of
complications from
bone metastases

Patient Information

Patient name	
Patient contact details	
Emergency contact details	
Specialist contact details	
GP contact details	
Nurse contact details	
Notes	

Introduction

Your doctor has prescribed XGEVA®

Your doctor will give you the XGEVA® package leaflet and a patient reminder card, which contains important safety information that you need to be aware of before and during your treatment with XGEVA®. These materials are also available here

Package leaflet:

<https://www.medicines.org.uk/emc/product/4675/pil>

Patient reminder card:

<https://www.medicines.org.uk/emc/rmm/240/Document>

In addition to the reminder card, the package leaflet and information provided by your healthcare professionals, this guide has further information to help you better understand what to expect during treatment with XGEVA®.

What is XGEVA®?¹

XGEVA® is made from a protein called denosumab. XGEVA® works by slowing down the bone destruction caused by cancer spreading to the bone (known as “bone metastasis”).

XGEVA® is used in adults with cancer to prevent serious complications caused by bone metastasis. These bone complications are called skeletal-related events, for example bone fractures, pressure on the spinal cord, and the need to receive radiation therapy or surgery to the bone.



When cancer spreads to the bone

Our bones are constantly changing – breaking down old bone and building up or reforming new bone. This means your bones are actually made up of a delicate balance of old and new bone.²

When cancer spreads to the bone, it may speed up the normal process of bone breakdown. An imbalance in this bone turnover process can lead to several complications.²

Impact of bone metastasis on your quality of life

Bone metastases can affect your quality of life, as it will have an impact on the strength and health of your bones, and can cause you significant pain.²

The consequences of bone metastases include:²

- Increased risk of fractures
- Abnormally high levels of calcium in the blood
- Spinal cord compression (harmful pressure on the spinal cord due to a spinal fracture, tumour or other lesion)
- Nerve compression (harmful pressure on a nerve)

Your doctor or nurse will be able to fully explain the potential consequences of bone metastases to you.

What do I need to know about XGEVA®?

As XGEVA® prevents your bones from breaking down, less calcium will be released from the bones into your blood. The calcium level in your blood should be measured before you start XGEVA® treatment.²

If your calcium level is low, your doctor may decide to give you calcium supplements before you start treatment with XGEVA®. During treatment with XGEVA®, your doctor will advise you to take calcium and vitamin D supplements, unless your calcium level is high.

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

Low calcium level in the blood (hypocalcaemia)

If you have spasms, twitches or cramps in your muscles, 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.¹

If you experience any of these symptoms, please contact your doctor immediately

Dental health¹

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

Before starting treatment:

- Check with your doctor whether a dental examination is recommended before you start treatment with XGEVA®.
- Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Patients undergoing dental surgery (e.g. tooth extractions), who do not receive routine dental care or have gum disease, smokers, or those who receive other medications affecting bone, may have a higher risk of developing ONJ.

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 and tell your dentist that you are being treated with XGEVA®.

You should 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 ONJ.

For information about other possible side effects not mentioned in this booklet, please refer to the Patient Information Leaflet: <https://www.medicines.org.uk/emc/product/4675/pil>



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. You can also report side effects directly via the Yellow Card Scheme at: <http://yellowcard.mhra.gov.uk/>

Or phone Amgen Ltd. UK and Ireland: +44 (0)1223 436441

By reporting side effects you can help provide more information on the safety of this medicine.

If you have any questions not answered by this leaflet, please contact your doctor:

Doctor's name	
Doctor's number	

Further resources:

Cancer Research UK

Tel: 020 7242 0200

Address: Angel Building, 407 St John Street,
London EC1V 4AD.

Macmillan Cancer Support

Tel: 080 8808 0000

Address: 89 Albert Embankment, London SE1 7UQ.

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References:

1. XGEVA® (denosumab), Patient Information Leaflet, Amgen.
2. Roodman GD. Mechanisms of bone metastasis. *N Engl J Med.* 2004;350:1655–1664.

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Oncology