Information for adult patients prescribed XGEVA® (denosumab) for the prevention of skeletal-related events caused by bone metastases



PATIENT INFORMATION





THE IMPACT OF BONE METASTASES

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. When cancer spreads to the bone (bone metastases), it may speed up the normal process of bone breakdown, causing bones to weaken over time. This can lead to several complications known as skeletal-related events. These include:

- Bone fractures
- Pressure on the spinal cord (spinal cord compression)
- A need to receive radiation therapy
- A need to receive surgery

Bone metastases and their associated complications can affect your quality of life and may cause you significant discomfort and pain.¹

Please talk to your doctor or nurse who will be able to discuss this in more detail and provide appropriate support.

YOUR DOCTOR HAS PRESCRIBED YOU TREATMENT TO HELP PREVENT SKELETAL-RELATED EVENTS

This guide contains information to help you better understand what to expect during your treatment. Your healthcare professional may also give you the Patient Information Leaflet and Patient Reminder Card, which contain important safety information that you need to be aware of before and during your treatment. These materials are also available here:

Patient Information Leaflet for the pre-filled syringe:

Great Britain: https://www.medicines.org.uk/emc/product/15535/pil;

N. Ireland: https://www.emcmedicines.com/en-gb/northernireland/medicine?id=ef1542d7-

4a16-4278-a3e6-3f6a7da17835&type=pil

Patient Information Leaflet for the vial:

Great Britain: https://www.medicines.org.uk/emc/product/4675/pil;

N. Ireland: https://www.emcmedicines.com/en-gb/northernireland/medicine?id=86ed122c-

a205-4f65-84ca-ba6d18f8b95b&type=pil

Patient Reminder Card for the pre-filled syringe:

Great Britain: https://www.medicines.org.uk/emc/product/15535/rmms;

N. Ireland: https://www.emcmedicines.com/en-gb/northernireland/medicine?id=ef1542d7-

4a16-4278-a3e6-3f6a7da17835&type=rmm

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a205-4f65-84ca-ba6d18f8b95b&type=rmm

WHAT IS XGEVA®?^{2,3}

XGEVA® is made from a protein called denosumab, which works by slowing down the breakdown of bone. This treatment is used in adults with cancer to prevent skeletal-related events, caused by bone metastases.

HOW IS MY TREATMENT ADMINISTERED?

This medicine (denosumab 120 mg) is an injection that is administered once every four weeks under the skin (subcutaneous) of your thigh, abdomen, or upper arm.^{2,3} XGEVA® is available as a 120 mg/1.7 mL solution in a single-use vial² or as a 120 mg/1.0 mL solution in a pre-filled syringe.³

Administration of the vial should only be performed by a healthcare professional.² The pre-filled syringe can be administered by a patient or caregiver who has been trained in injection techniques by a healthcare professional.³ The first self administration with the XGEVA® pre-filled syringe should be supervised by a healthcare professional.³

The diary below can help you to keep track of your schedule. Please take it with you to your doctor's appointment or complete after self-administration to remind you of your next dose.

Injection date	Injection dose	Notes

Injection date	Injection dose	Notes

WHAT DO I NEED TO KNOW ABOUT MY TREATMENT?

CALCIUM AND VITAMIN D SUPPLEMENTATION

As denosumab 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 treatment.²

If your calcium level is low, your doctor may decide to give you calcium supplements before you start treatment. During treatment, your doctor will advise you to take calcium and vitamin D supplements, unless your calcium level is high.²

LOW CALCIUM LEVEL IN THE BLOOD (HYPOCALCAEMIA)²

Please tell your doctor immediately 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. You may have low levels of calcium in your blood.

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

RENAL IMPAIRMENT

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.²

DENTAL HEALTH^{3,4}

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 denosumab injections for cancer-related conditions.^{3,4} ONJ can also occur after stopping treatment.^{3,4} 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.^{3,4}
- Tell your doctor/nurse (healthcare professional) if you have any problems with your mouth or teeth.^{3,4}
- Your doctor should delay the start of your treatment if you have unhealed wounds in your mouth from dental procedures or oral surgery.³

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.^{2,3}

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 receiving dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with denosumab.

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, and non-healing of sores or discharge, as these could be signs of ONJ.

Please note: Denosumab is not recommended for use in pregnancy or in women of child-bearing potential not using contraception.

For information about other possible side effects not mentioned in this booklet, please refer to the **Patient Information Leaflet**.



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

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.

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

Macmillan Cancer Support

Tel: 0300 123 1022

NOTES NOTES

REFERENCES

- 1. Roodman GD. Mechanisms of bone metastasis. N Engl J Med. 2004;350:1655–1664.
- 2. XGEVA® (denosumab) vial, Patient Information Leaflet, Amgen.
- 3. XGEVA® (denosumab) pre-filled syringe, Patient Information Leaflet, Amgen.
- 4. XGEVA® (denosumab) Patient Reminder Card.

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