

PATIENT REMINDER CARD

Important Safety Information

Patient reminder card regarding osteonecrosis of the jaw (ONJ)

This reminder card contains important safety information that you need to be aware of before and during treatment with denosumab (XGEVA) injections for cancer-related conditions

Your doctor has recommended that you receive denosumab (XGEVA) injections which is used in adults with 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.

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 (XGEVA) injections for cancer-related conditions. 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 denosumab (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, are smokers, who get different types of cancer treatments 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 denosumab (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 ONJ.
- Patients undergoing chemotherapy and/or radiotherapy, are taking steroids or anti-angiogenic medicines (used to treat cancer), undergoing dental surgery, who do not receive routine dental care or have gum disease, are smokers may have a higher risk of developing osteonecrosis of the jaw.

Please read the package leaflet that comes with your medicine for further information

Any suspected adverse reactions should be reported immediately to Amgen local representative or to the National Pharmacovigilance and Drug Safety Centre.

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