

# XGEVA® (DENOSUMAB)

## INFORMATION TO GIVE TO YOUR DENTIST:

**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<sup>1,2</sup>
- 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

## 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 whilst 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](http://www.ADEE.org) for more information on ONJ

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](http://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.

### References:

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