XGEVA®
denosumab

ESMO RECOMMENDED BTA
for Bone Metastases[1]

2020 ESMO Clinical Practice Guidelines Recommended Use of BTAs[1]

- Initiate BTA at diagnosis of bone metastasis
- Use throughout the course of the disease

XGEVA® is the preferred BTA from efficacy, convenience and renal health perspectives[1]

The Trusted Partner with Proven Clinical Benefit[1]

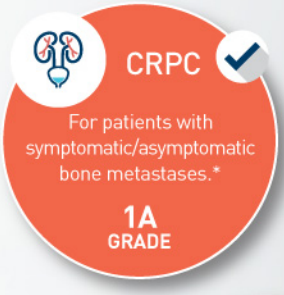
	XGEVA®
Breast Cancer • **Superior** in delaying time to 1st and subsequent SRE[1] & delayed worsening of bone pain vs ZA[1]	✓
Lung Cancer • Suggested **survival improvement** in NSCLC patients[1*]	✓
CRPC • **18%** risk reduction in cumulative SRE vs ZA[1]	✓
Multiple Myeloma • The **agent of choice** in patients with renal impairment (creatinine clearance <60 ml/min)[1] • Extended mPFS by **10.7 months** vs ZA[1]	✓

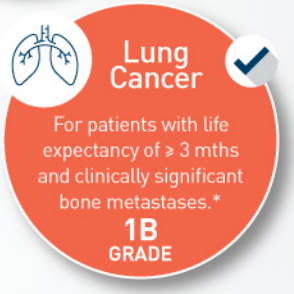
*An exploratory analysis of the patients with NSCLC. This observation was not supported by recently reported SPLENDOUR trial.

ZA=Zoledronic Acid

ESMO RECOMMENDATIONS OF XGEVA®

Across Tumor Types[1]





Administer XGEVA® every 4 weeks for maximal benefit
Extending intervals beyond this frequency is not recommended[1]

BTA=bone-targeted agent; CRPC=castration-resistant prostate cancer; MM=multiple myeloma; NSCLC= non-small-cell lung cancer; SRE= skeletal related event
*Zoledronic acid is another recommended BTA for patients with corresponding conditions[1].
Reference: 1. Coleman R, et al. Ann Oncol. 2020;31:1650-1663.

XGEVA® [denosumab] Abbreviated Prescribing Information
XGEVA® [denosumab] Solution for Injection 120 mg
INDICATIONS Indicated for prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone, and treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity. DOSAGE AND ADMINISTRATION Supplementation of at least 500 mg calcium and 400 IU vitamin D daily is required in all patients, unless hypercalcaemia is present. Prevention of skeletal related events in adults with advanced malignancies involving bone: The recommended dose is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm. Giant cell tumour of bone: The recommended dose of XGEVA is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm with additional 120 mg doses on days 8 and 15 of treatment of the first month of therapy. Renal impairment: No dose adjustment is required in patients with renal impairment; Hepatic impairment: The safety and efficacy of denosumab have not been studied in patients with hepatic impairment. Elderly patients (age ≥ 65): No dose adjustment is required in elderly patients. Paediatric population: XGEVA is not recommended in paediatric patients (age < 18) other than skeletally mature adolescents (aged 12-17 years) with giant cell tumour of bone. CONTRAINDICATIONS Contraindicated in patients with hypersensitivity to the active substance or to any of the excipients, and in patients with severe, untreated hypocalcaemia. Contraindicated in patients with unhealed lesions from dental or oral surgery. SPECIAL WARNINGS AND PRECAUTIONS FOR USE Calcium and Vitamin D supplementation: Supplementation with calcium and vitamin D is required in all patients unless hypercalcaemia is present. Hypocalcaemia: Pre-existing hypocalcaemia must be corrected prior to initiating therapy with XGEVA. Hypocalcaemia can occur at any time during therapy with XGEVA. Renal impairment: Patients with severe renal impairment (creatinine clearance < 30 ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia. Osteonecrosis of the jaw (ONJ): ONJ has been reported commonly in patients receiving XGEVA. The start of treatment/ new treatment course should be delayed in patients with unhealed open soft tissue lesions in the mouth. A dental examination with preventive dentistry and an individual benefit-risk assessment is recommended prior to treatment with XGEVA. Multiple Vertebral Fractures (MVF) Following of Treatment Discontinuation: MVF, not due to bone metastases, may occur following discontinuation of treatment with Xgeva, particularly in patients with risk factors such as osteoporosis or prior fractures. Advise patients not to interrupt Xgeva therapy without their physician's advice. Osteonecrosis of the external auditory canal: Osteonecrosis of the external auditory canal has been reported with denosumab. Possible risk factors include steroid use and chemotherapy and/or local risk factors such as infection or trauma. Atypical fractures of the femur: Atypical femoral fractures have been reported in patients receiving XGEVA. Atypical femoral fractures may occur with little or no trauma in the subtrochanteric and diaphyseal regions of the femur. Hypercalcaemia following treatment discontinuation in patients with giant cell tumour of bone and in patients with growing skeleton: Clinically significant hypercalcaemia requiring hospitalisation and complicated by acute renal injury has been reported in XGEVA-treated patients with giant cell tumour of bone weeks to months following treatment discontinuation. After treatment is discontinued, monitor patients for signs and symptoms of hypercalcaemia. XGEVA is not recommended in patients with growing skeletons. Clinically significant hypercalcaemia has been reported in XGEVA-treated patients with growing skeletons weeks to months following treatment discontinuation. Others: Patients being treated with XGEVA should not be treated concomitantly with other denosumab containing medicinal products, or with bisphosphonates. INTERACTIONS No interaction studies have been performed. PREGNANCY, LACTATION AND FERTILITY Pregnancy: There are no or limited amount of data from the use of denosumab in pregnant women. XGEVA is not recommended for use in pregnant women and women of childbearing potential not using contraception. Breast-feeding: It is unknown whether denosumab is excreted in human milk. A risk to the newborns/infants cannot be excluded. Fertility: No data are available on the effect of denosumab on human fertility.
UNDESIRABLE EFFECTS Hypocalcaemia has very commonly been reported following XGEVA administration, mostly within the first 2 weeks. The most common adverse reactions with XGEVA are musculoskeletal pain. Cases of osteonecrosis of the jaw have been commonly observed in patients taking XGEVA. The adverse reactions identified in clinical trials and from post-marketing experience: Very common (≥ 1/10) adverse reactions include: hypocalcaemia, dyspnoea, diarrhoea and musculoskeletal pain. Common (≥ 1/100 to < 1/10) adverse reactions include: new primary malignancy, hypophosphataemia, tooth extraction, alopecia, hyperhidrosis and osteonecrosis of the jaw. OVERDOSE There is no experience with overdose in clinical studies.
Abbreviated Prescribing Information Version: HKXGEPI04

Please read the full prescribing information prior to administration and full prescribing information is available on request.
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For medical inquiries or to report adverse events/product complaint, please contact [+852] 800 961 142 or email medinfo_JAPAC@amgen.com.
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XGEVA® denosumab

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