

XGEVA[®]

(denosumab)

Subcutaneous injection.

XGEVA[®] PRODUCT FACT SHEET

INDICATION

XGEVA[®] is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

PRODUCT INFORMATION

NDC	Description	Quantity
55513-730-01	120 mg/1.7 mL single-use vial	One per carton



Use a 27-gauge needle to withdraw and inject the entire contents of the vial. Syringe must be purchased separately.

STORAGE AND HANDLING REQUIREMENTS

Store XGEVA[®] in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Once removed from the refrigerator, XGEVA[®] must not be exposed to temperatures above 25°C/77°F or direct light and must be used within 14 days. Discard XGEVA[®] if not used within the 14 days. Do not use XGEVA[®] after the expiry date printed on the label.

Protect XGEVA[®] from direct light and heat.

Avoid vigorous shaking of XGEVA[®].

SHIPPING CONTAINER INFORMATION

XGEVA[®] should be unpacked and refrigerated.

XGEVA[®] should not be stored in the shipping container.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.

www.amgen.com www.XGEVA.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Returned Goods Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Amgen Assist[®]: 1-888-4ASSIST (1-888-427-7478) or www.AmgenAssistOnline.com

Please see Important Safety Information on next page.

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IMPORTANT SAFETY INFORMATION

• Hypocalcemia

Pre-existing hypocalcemia must be corrected prior to initiating therapy with XGEVA[®]. XGEVA[®] can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Monitor calcium levels, especially in the first weeks of initiating therapy, and administer calcium, magnesium, and vitamin D as necessary. Concomitant use of calcimimetics and other drugs that can lower calcium levels may worsen hypocalcemia risk and serum calcium should be closely monitored. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

• Hypersensitivity

XGEVA[®] is contraindicated in patients with known clinically significant hypersensitivity to XGEVA[®], including anaphylaxis that has been reported with use of XGEVA[®]. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue XGEVA[®] therapy permanently.

• Drug Products with Same Active Ingredient

Patients receiving XGEVA[®] should not take Prolia[®] (denosumab).

• Osteonecrosis of the Jaw

Osteonecrosis of the jaw (ONJ) has been reported in patients receiving XGEVA[®], manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure.

Patients with a history of tooth extraction, poor oral hygiene, or use of a dental appliance are at a greater risk to develop ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.

Perform an oral examination and appropriate preventive dentistry prior to the initiation of XGEVA[®] and periodically during XGEVA[®] therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with XGEVA[®]. Consider temporarily interrupting XGEVA[®] therapy if an invasive dental procedure must be performed.

Patients who are suspected of having or who develop ONJ while on XGEVA[®] should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

• Atypical Subtrochanteric and Diaphyseal Femoral Fracture

Atypical femoral fracture has been reported with XGEVA[®]. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.

Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture. During XGEVA[®] treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patients presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of XGEVA[®] therapy should be considered, pending a risk/benefit assessment, on an individual basis.

• Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons

Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in XGEVA[®]-treated patients with GCTB and in patients with growing skeletons within one year of treatment discontinuation. Monitor patients for signs and symptoms of hypercalcemia after treatment discontinuation and treat appropriately.

• Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

Multiple vertebral fractures (MVF) have been reported following discontinuation of treatment with denosumab. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When XGEVA[®] treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

• Embryo-Fetal Toxicity

XGEVA[®] can cause fetal harm when administered to a pregnant woman. Based on findings in animals, XGEVA[®] is expected to result in adverse reproductive effects.

Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of XGEVA[®]. Apprise the patient of the potential hazard to a fetus if XGEVA[®] is used during pregnancy or if the patient becomes pregnant while patients are exposed to XGEVA[®].

• Adverse Reactions

The most common adverse reactions in patients receiving XGEVA[®] with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea. The most common adverse reactions resulting in discontinuation were osteonecrosis and hypocalcemia.

For multiple myeloma patients receiving XGEVA[®], the most common adverse reactions were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation of XGEVA[®] was osteonecrosis of the jaw.

Please click here for Prescribing Information.

1. Prescribing Information, XGEVA[®].



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