Denosumab

Pronunciation: *den-OH-sue-mab*
Generic name: denosumab
Brand names: Prolia, Bomyntra, Conexxence, Jubbonti, Osenvelt, ... show all 10 brands
Dosage form: single-use vial for intravenous infusion (Xgeva, 120 mg/1.7 mL), single-use prefilled syringe (Prolia 60 mg/1 mL; Xgeva 120 mg/1.7 mL)
Drug class: Miscellaneous bone resorption inhibitors

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What is denosumab?

Denosumab is a human monoclonal antibody that works by inhibiting RANKL (receptor activator of nuclear factor kappa-B ligand), a protein essential for osteoclasts' formation, function, and survival.

- By inhibiting RANKL, denosumab decreases bone resorption and increases bone mass and strength.

In the United States, denosumab is marketed under the following brand names and biosimilars:

- Prolia (biosimilars Conexxence, Jubbonti, Ospomyv, and Stoboclo) for osteoporosis-related conditions
- Xgeva (biosimilars Bomyntra, Osenvelt, Wyost, and Xbryk) for the prevention of skeletal-related events due to certain cancers, or as a second-line treatment for hypercalcemia of malignancy.

Prolia (denosumab)

There are currently 4 biosimilars to Prolia:

- Jubbonti (denosumab-bbdz) made by Sandoz Inc. (FDA approval March 5, 2024).
- Ospomyv (denosumab-dssb) made by Samsung Bioepis (FDA approval February 16, 2025)
- Stoboclo (denosumab-bmwo) made by Celltrion (FDA approval February 28, 2025)
- Conexxence (denosumab-bnht) made by Fresenius Kabi (FDA approval March 25, 2025).

FDA-Approved Indications for Prolia

- **Postmenopausal Osteoporosis**: Treatment of postmenopausal women with osteoporosis at high risk for fracture
- **Male Osteoporosis**: Treatment of men with osteoporosis at high risk for fracture
- **Glucocorticoid-Induced Osteoporosis**: Treatment of men and women at high risk of fracture who are receiving

systemic glucocorticoids

- **Bone Loss in Hormone Ablation Therapy**:
  - Treatment of men receiving androgen deprivation therapy for nonmetastatic prostate cancer
  - Treatment of women receiving adjuvant aromatase inhibitor therapy for breast cancer.

Dosage for Prolia

Standard Dosage: 60 mg administered as a subcutaneous injection once every 6 months.

Administration: Given by a healthcare professional in the upper arm, upper thigh, or abdomen.

Common Side Effects of Prolia

- Back pain
- Pain in extremities
- Musculoskeletal pain
- Hypercholesterolemia
- Cystitis.

Serious Side Effects of Prolia

- Hypocalcemia (low blood calcium)
- Serious infections
- Dermatologic reactions (dermatitis, rashes, eczema)
- Osteonecrosis of the jaw (ONJ)
- Atypical femoral fractures
- Multiple vertebral fractures following discontinuation
- Suppression of bone turnover.

Xgeva (denosumab)

There are currently 4 biosimilars to Xgeva:

- Wyost (denosumab-bbdz) made by Sandoz Inc. (FDA approval March 5, 2024)
- Xbryk (denosumab-dssb) made by Samsung Bioepis (FDA approval February 16, 2025)
- Osenvelt (denosumab-bmwo) made by Celltrion (FDA approval February 28, 2025)
- Bomyntra (denosumab-bnht) made by Fresenius Kabi (FDA approval March 25, 2025).

FDA-Approved Indications for Xgeva and its biosimilars

- **Prevention of Skeletal-Related Events**: In patients with bone metastases from solid tumors
- **Giant Cell Tumor of Bone**: Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that

is unresectable or where surgical resection is likely to result in severe morbidity

- **Hypercalcemia of Malignancy**: Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Dosage for Xgeva and its biosimilars

For Prevention of Skeletal-Related Events: 120 mg administered as a subcutaneous injection every 4 weeks

For Giant Cell Tumor of Bone: 120 mg administered as a subcutaneous injection every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first month of therapy

For Hypercalcemia of Malignancy: 120 mg administered as a subcutaneous injection every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first month of therapy.

Common Side Effects of Xgeva

- Fatigue/lack of energy
- Low phosphate levels
- Nausea
- Joint pain
- Headache.

Serious Side Effects of Xgeva

- Low calcium levels (more common and potentially more severe than with Prolia)
- Osteonecrosis of the jaw (more frequent than with Prolia)
- Stress fractures in the femur bone
- Harm to an unborn baby
- Increased risk of a new cancer(in patients with multiple myeloma).

Warnings for denosumab

Both Prolia and Xgeva carry a boxed warning for life-threatening severe hypocalcemia (very low calcium levels) in patients with advanced chronic kidney disease (CKD), particularly those on dialysis.

- The risk is even greater in those patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD).
- Your healthcare provider will evaluate you for CKD-MBD before starting treatment, and monitor you throughout.

Essential Information Before Starting Denosumab

Pre-Treatment Assessments

- Calcium Levels: Hypocalcemia must be corrected before initiating therapy
- Renal Function: Patients with severe renal impairment or receiving dialysis are at greater risk for hypocalcemia

- Dental Examination: A comprehensive dental exam is recommended before starting therapy, especially for patients with risk factors for ONJ
- Vitamin D Status: Assessment and correction of vitamin D deficiency
- Pregnancy Testing: For women of childbearing potential.

Supplementation Requirements

Calcium: All patients should take calcium supplements

- Prolia patients: 1000 mg of calcium daily
- Xgeva patients: 500 mg of calcium daily (or as directed by healthcare provider).

Vitamin D: All patients should take vitamin D supplements

- Recommended daily intake: 400-800 IU for most patients
- Higher doses may be needed for patients with a deficiency.

Related/similar drugs

Prolia

Prolia (denosumab) is an injection that is administered subcutaneously (under the skin) once every ...

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Contraindications

- Low calcium levels (hypocalcemia): Denosumab is contraindicated in patients with pre-existing hypocalcemia
- Pregnancy: Denosumab is contraindicated during pregnancy
- Hypersensitivity: Known hypersensitivity to denosumab or any of its excipients.

Special Populations

Pediatric Patients:

- Prolia is not recommended for pediatric populations
- Xgeva is approved only for skeletally mature adolescents with giant cell tumor of bone.

Elderly Patients:

- No dosage adjustment required based on age
- Higher incidence of certain adverse reactions may occur.

Renal Impairment:

- No dosage adjustment necessary
- Greater risk for hypocalcemia; monitoring required.

Hepatic Impairment:

- No studies conducted
- Unlikely to require dose adjustment as denosumab is a monoclonal antibody not cleared by hepatic mechanisms.

Important Monitoring During Treatment

Calcium Levels:

- For Prolia: Monitor calcium before each dose and within 2 weeks after the initial dose in patients at risk for hypocalcemia
- For Xgeva: Monitor calcium prior to initial dose, within the first week, and for hypocalcemia symptoms throughout therapy.

Dental Health:

- Regular dental checkups
- Maintain good oral hygiene
- Report any dental symptoms promptly.

Bone Turnover Markers:

- May be monitored in some patients to assess treatment response.

Adverse Reactions:

Monitor for signs of infection, dermatological reactions, and musculoskeletal pain.

Discontinuation Considerations

Prolia Discontinuation:

- Increased risk of vertebral fractures, often multiple, following discontinuation
- Consider alternative therapy if Prolia is discontinued
- No established recommendations for a drug holiday (unlike bisphosphonates).

Transition Between Therapies:

Specific protocols may be needed when transitioning from or to other osteoporosis medications.

Drug Interactions

- Limited drug interactions due to the monoclonal antibody nature of denosumab
- No formal drug interaction studies have been conducted
- Caution with immunosuppressants due to potential increased risk of infection.

Denosumab drug interactions (more detail)

Does denosumab interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

denosumab

+

Enter a drug name Add

Patient Counseling Information

Hypocalcemia Risk:

- Importance of calcium and vitamin D supplementation
- Symptoms to watch for (muscle spasms, twitches, cramps, numbness or tingling).

Osteonecrosis of the Jaw Prevention:

- Maintain good oral hygiene
- Schedule routine dental exams
- Inform your dentist about denosumab treatment
- Avoid invasive dental procedures if possible.

Atypical Fracture Awareness:

- Report new or unusual thigh, hip, or groin pain.

Infection Risk:

Seek prompt medical attention for signs of infection (fever, chills, severe abdominal pain, skin issues).

Pregnancy Considerations:

- Avoid pregnancy during treatment
- Use effective birth control while using denosumab and for 5 months after your last dose
- Report suspected pregnancy immediately.

Denosumab Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 2 for denosumab.

Prolia (denosumab) - Amgen Inc.

Formulation type	Strength
Pre-Filled Syringe	60 mg/mL
Single-Dose Vial	60 mg/mL **Discontinued**

View Prolia information in detail.

Xgeva (denosumab) - Amgen Inc.

Prolia, Xgeva interchangeable products

Interchangeable biosimilar products can be dispensed by a pharmacist without the intervention of the prescriber of the reference product.

Pharmacy laws for biosimilar prescribing may vary by state.

Jubbonti (denosumab-bbdz) - Sandoz Inc.

Wyost (denosumab-bbdz) - Sandoz Inc.

Popular FAQ

How long should you take Xgeva for?

Is Xgeva a chemotherapy drug?

Does Xgeva cause bone pain?

Does Xgeva cause low blood pressure?

More FAQ

- How many years should you take Prolia?

View more FAQ…

References

1. Prolia (denosumab) Package Insert
2. Xgeva (denosumab) Package Insert

More about denosumab

- Check interactions
- Compare alternatives
- Reviews (396)
- Latest FDA alerts (1)
- Side effects
- Dosage information
- Patient tips
- During pregnancy
- Drug class: miscellaneous bone resorption inhibitors
- Breastfeeding
- En español

Patient resources

Other brands

Prolia, Xgeva, Jubbonti, Wyost

Professional resources

- Denosumab monograph

Other brands

Prolia, Xgeva

Related treatment guides

- Osteolytic Bone Metastases of Solid Tumors
- Osteoporosis
- Giant Cell Tumor of Bone
- Hypercalcemia of Malignancy
- Osteolytic Bone Lesions of Multiple Myeloma

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability
Rx Prescription only

Pregnancy & Lactation
Risk data available

CSA Schedule*
N/A Not a controlled drug

Approval History
Drug history at FDA

User Reviews & Ratings

3.0 / 10

396 Reviews

Related News

FDA Approves Bomyntra (denosumab-bnht), a Biosimilar to Xgeva

FDA Approves Conexxence (denosumab-bnht), a Biosimilar to Prolia

FDA Approves Osenvelt (denosumab-bmwo), a Biosimilar to Xgeva

Images

Prolia (denosumab) 60 mg/1 mL in a single-dose prefilled syringe

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