Bomyntra®
denosumab-bnht

FDA-approved biosimilar to Xgeva® (denosumab)[1]
Available as a prefilled syringe or vial

Maintain movement. Prevent fractures.

Help protect bones and preserve mobility

INDICATIONS:

BOMYNTRA® (denosumab-bnht) is indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- 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.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Hypocalcemia

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Bomyntra (denosumab-bnht).

Hypersensitivity

Bomyntra is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

WARNINGS AND PRECAUTIONS

Drug Products with Same Active Ingredient

Patients receiving Bomyntra should not receive other denosumab products concomitantly.

Hypersensitivity

Clinically significant hypersensitivity including anaphylaxis has been reported with use of denosumab products. 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 Bomyntra therapy permanently.

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information for BOMYNTRA® (denosumab-bnht).

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FDA APPROVED

Clinical development ensured that BOMYNTRA® (denosumab-bnht) met FDA requirements for biosimilarity[1-5]

FDA Requirements for Biosimilar Approval	BOMYNTRA®
Analytical characterization (primary structure, potency, and purity)	✓
Nonclinical studies	✓
Clinical pharmacology	✓
Comparative clinical study	✓
BOMYNTRA® was studied in a Phase III study with a switching arm[4]	

FDA approved based on proven similarity to Xgeva® (denosumab) in[1-5]:

- Analytical characterization
- Pharmacokinetics/pharmacodynamics
- Efficacy, safety, and immunogenicity

Demonstrated efficacy at year 1 with similar efficacy in patients who switched to BOMYNTRA®[4]*

* BOMYNTRA® is FDA approved for the same indications as Xgeva®. Based on extrapolation, clinical data demonstrating similar safety and efficacy compared to Prolia® supported the approval.

FDA = US Food and Drug Administration.

Important Safety Information (continued)

Hypocalcemia

Denosumab products can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Correct pre-existing hypocalcemia prior to Bomyntra treatment. Monitor calcium levels, throughout Bomyntra therapy, 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 provider for symptoms of hypocalcemia.

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ADMINISTRATION OPTIONS

BOMYNTRA® (denosumab-bnht) is the first 120 mg denosumab biosimilar in the U.S. available in 2 presentations[1,2]

Single-Dose Prefilled Syringe

Single-Use Vial

Prefilled Syringe[1,2]	
Feature	**BOMYNTRA®**
Volume	120 mg/1.7 mL
Needle Guard	Automatic
Needle Gauge	27-gauge needle
Room Temperature Storage	14 days at 77°F (25°C)
Shelf Life	30 months

Vial[1-3]		
Feature	**BOMYNTRA®**	**Xgeva®**
Volume	120 mg/1.7 mL	120 mg/1.7 mL
Pack Size	1	1
Room Temperature Storage	14 days at 77°F (25°C)	30 days at 77°F (25°C)
Shelf Life	30 months	48 months

Important Safety Information (continued)

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/min and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

Osteonecrosis of the Jaw (ONJ)

ONJ has been reported in patients receiving denosumab products, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection,

DOSING AND ADMINISTRATION

BOMYNTRA® (denosumab-bnht) has the same dosing as Xgeva® (denosumab)[1-3]

Recommended Dosing		
Indication	**Dosage and Frequency**	**Additional Instructions**
Multiple Myeloma and Bone Metastasis from Solid Tumors	120 mg administered every 4 weeks	Administer calcium and vitamin D as needed to treat or prevent hypocalcemia
Giant Cell Tumor of Bone	120 mg administered every 4 weeks (with 120 mg doses on Days 8 and 15 of the first month of therapy)	Administer calcium and vitamin D as needed to treat or prevent hypocalcemia
Hypercalcemia of Malignancy	120 mg administered every 4 weeks (with 120 mg doses on Days 8 and 15 of the first month of therapy)	No additional instructions

Important Safety Information (continued)

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 Bomyntra and periodically during Bomyntra therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with Bomyntra. Consider temporary discontinuation of Bomyntra therapy if an invasive dental procedure must be performed.

Patients who are suspected of having or who develop ONJ while on Bomyntra 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 denosumab products. 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

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At Fresenius Kabi, our global expertise in complex medicine, state-of-the-art supply chain, and manufacturing allow us to deliver consistent quality biosimilars.

A strong history of scientific expertise, quality manufacturing, and reliable supply

A robust portfolio of **FDA-approved biosimilars in oncology, immunology, and bone health**

Multiple additional biosimilars in development

Winner of Numerous Awards[2]

Important Safety Information (continued)

patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture.

During Bomyntra 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. Patient presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of Bomyntra 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 denosumab product-treated patients with GCTB and patients with growing skeletons within the first year after treatment

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discontinuation. After treatment is discontinued, monitor patients for signs and symptoms of hypercalcemia and manage patients as clinically appropriate.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

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

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of action, denosumab products can cause fetal harm when administered to a pregnant woman.

Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of Bomyntra. Advise pregnant women and females of reproductive potential that exposure to Bomyntra during pregnancy or within 5 months prior to conception can result in fetal harm.

ADVERSE REACTIONS

The most common adverse reactions in patients receiving denosumab 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.

The most common adverse reactions in patients receiving denosumab with multiple myeloma 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 denosumab was osteonecrosis of the jaw.

The most common adverse reactions in patients with giant cell tumor of bone were arthralgia, back pain, pain in extremity, fatigue, headache, nausea, nasopharyngitis, musculoskeletal pain, toothache, vomiting, hypophosphatemia, constipation, diarrhea, and cough. The most frequent serious adverse reactions were osteonecrosis of the jaw, bone giant cell tumor, anemia, pneumonia, and back pain. The most frequent adverse reactions resulting in discontinuation of denosumab was osteonecrosis of the jaw.

The most common adverse reactions in patients with hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea. The following adverse reactions of Grade 3 or greater severity related to study therapy were reported on-study: fatigue and infection. Grade 3 laboratory abnormalities included hypomagnesemia, hypokalemia, and hypophosphatemia. No deaths on-study were related to denosumab therapy

INDICATIONS

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NOTES

BOMYNTRA® (denosumab-bnht): Maintain movement. Prevent fractures.

No clinically meaningful differences to Xgeva® (denosumab)*[1-5]

The first 120 mg denosumab available in the U.S. in both a vial and a prefilled syringe[1,2]

Safe and effective switching to BOMYNTRA®[4]

A potentially cost-effective option that may increase access to denosumab

Prefilled syringe is equipped with a 27-gauge thin-wall needle and automatic needle safety guard[1,2]

*BOMYNTRA® is FDA approved for the same indications as Xgeva®. Based on extrapolation, clinical data demonstrating similar safety and efficacy compared to Prolia® supported the approval.

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References: 1. BOMYNTRA®. Package insert. Fresenius Kabi USA, LLC; 2025. **2.** Data on file. Fresenius Kabi. **3.** Xgeva®. Package insert. Amgen Inc; 2024. **4.** Sadek J, Valter I, de Souza A, Szeles P, Monnet J. A randomized, double-blind, study to evaluate the efficacy, pharmacodynamics, safety and immunogenicity of FKS518 proposed biosimilar to denosumab with the originator in postmenopausal women with osteoporosis (LUMIADE-3 study). *Journal of Clinical Oncology*. 2024;42(16_suppl):3155-3155. doi:10.1200/jco.2024.42.16_suppl.3155. **5.** Sadek J, Dryja A, Szeles P, Buccarello AL, Monnet J. A double-blind, randomized, two-arm, single-dose, parallel-group study in healthy participants to compare the pharmacokinetics, pharmacodynamics, and immunogenicity of FKS518 proposed biosimilar to denosumab with the originator (LUMIADE-1 study). *Journal of Clinical Oncology*. 2024;42(16_suppl). doi:10.1200/jco.2024.42.16_suppl.e15097.

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