Bomyntra®
denosumab-bnht

# Your treatment journey with BOMYNTRA®(denosumab-bnht)

## Important Safety Information

**Do not take Bomyntra (denosumab-bnht) if you have low blood calcium (hypocalcemia).** Your low blood calcium must be treated before you receive Bomyntra. Denosumab can significantly lower the calcium levels in your blood and some deaths have been reported. Take calcium and vitamin D as your doctor tells you to. Tell your doctor right away if you experience spasms, twitches, cramps, or stiffness in your muscles or numbness or tingling in your fingers, toes, or around your mouth.

**Do not take Bomyntra if you are allergic to denosumab or any of the ingredients of Bomyntra.** Serious allergic reactions have happened in people who take denosumab. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction, including low blood pressure (hypotension); trouble breathing; throat tightness; swelling of the face, lips, or tongue, rash; itching; or hives.

**What is the most important information you should know about Bomyntra?**

**Do not take Bomyntra if you take other denosumab products.** Patients receiving Bomyntra should not receive other denosumab products at the same time.

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

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## What is BOMYNTRA® (denosumab-bnht)?[1,2]

BOMYNTRA® (denosumab-bnht) is an FDA-approved biosimilar to Xgeva® (denosumab).

BOMYNTRA® is a prescription medicine used for:

- Fracture prevention, spinal cord compression, or the need for radiation or surgery to bone 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 (continued)**

**Severe jaw bone problems (osteonecrosis)**
Severe jaw bone problems may happen when you take Bomyntra. Your doctor should examine your mouth before you start, and while you are taking Bomyntra. Tell your dentist that you are taking Bomyntra. It is important for you to practice good mouth care during treatment with Bomyntra. In studies of patients with bone involvement, the rate of severe jaw problems was higher the longer they were being treated with denosumab.

**Unusual thigh bone fracture**
Unusual thigh bone fracture has been reported in patients receiving denosumab. Symptoms of a fracture include new or unusual pain in your hip, groin, or thigh.

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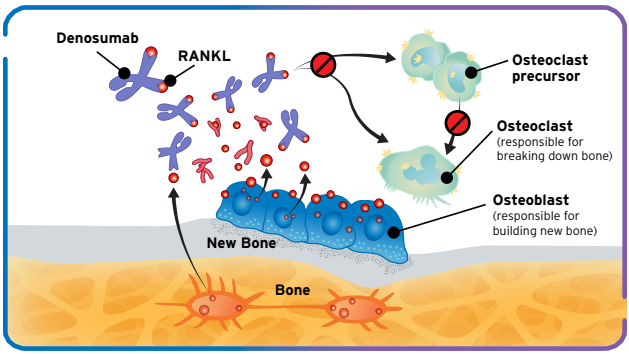
## Why do I need BOMYNTRA® (denosumab-bnht)?[1,3]

Denosumab helps strengthen bones by slowing the activity of specific bone cells, called osteoclasts, that breakdown bone material. Bone health is maintained through a constant cycle of building bone and breaking down bone.

BOMYNTRA® may help prevent bone problems in patients with multiple myeloma, bone metastases from solid tumors and giant cell tumor of bone.

## How does BOMYNTRA® work?[1]

BOMYNTRA® blocks RANKL*, a protein that tells bone cells, called osteoclasts, to break down bone. By stopping RANKL, it helps keep bones from breaking down too quickly, which protects your bones and makes them stronger with more mass.




*RANKL = Receptor Activator of NF-kB Ligand

**Important Safety Information (continued)**

**Risk of high calcium levels in patients with Giant Cell Tumor of Bone and in patients who are still growing**
Patients with a type of cancer called Giant Cell Tumor of Bone and patients with bones that are not fully matured are at a greater risk to develop high blood calcium levels after they stop taking Bomyntra, that can be serious.

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## What does it mean if your prescription medicine is an FDA-approved biosimilar?[1,2,4]

An FDA-approved biosimilar means that there are no clinically meaningful differences in effectiveness, safety, or purity between the biosimilar, like BOMYNTRA® (denosumab-bnht), and the reference (original) product, like Xgeva® (denosumab). Biosimilars are safe and effective.

### BOMYNTRA® and Xgeva® are similar in the following ways:

- Made from living cells
- Given the same way
- Provide the same treatment benefits
- Have the same potential side effects

However, biosimilars can be different in an important aspect of care that impacts everyone–cost. Biosimilars, like BOMYNTRA®, may be less expensive than reference (original) products, like Xgeva®, which helps make critical medicines accessible to more patients.


**On average, biosimilars frequently offer more than 40% price reductions compared with reference products[5]**

**Important Safety Information (continued)**

**Increased risk of broken bones in the spine after discontinuing Bomyntra**
After your treatment with Bomyntra is stopped, your risk for breaking bones in your spine can increase, especially if you have a history of risk factors such as osteoporosis or prior fractures.

**Possible harm to your unborn baby**
You should not become pregnant while taking Bomyntra. Tell your doctor right away if you are pregnant, plan to become pregnant, or suspect you are pregnant. Bomyntra can harm your unborn baby.

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## How do I take BOMYNTRA® (denosumab-bnht)?[1]

Your healthcare provider will give you 120 mg of medicine as a single injection under your skin in the upper arm, the upper thigh, or the abdomen.

You will get the injection in your healthcare provider's office or at an infusion center.

## How much BOMYNTRA® will I receive, and how often will I need it?[1]

Your BOMYNTRA® treatment plan is shown in the table below.

| 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 |

### Helpful Reminders:

**Don't Wait If You Miss an Injection**
If you miss an injection, contact your healthcare provider's office as soon as possible to reschedule and receive the missed dose.

**Mark Your Calendar**
To stay on track and avoid missing your next dose, mark your calendar for the next scheduled injection date.

## Helpful Patient Resources

The following materials may help you during your treatment with BOMYNTRA® (denosumab-bnht).

### Understanding biologics and biosimilars

This brochure provides answers to frequently asked questions about biosimilars.


### BOMYNTRA.com

The website has important information about BOMYNTRA® and helpful tips to support you during your treatment.


**Important Safety Information (continued)**

**Tell your doctor if you:**

- Are taking other denosumab products.
- Have symptoms of low blood calcium such as muscle stiffness or cramps
- Have symptoms of severe jaw bone problems such as pain or numbness
- Have ongoing pain or slow healing after dental surgery
- Have symptoms of high blood calcium such as nausea, vomiting, headache, and decreased alertness
- Are pregnant, plan to become pregnant, suspect you are pregnant, or breastfeeding

**While taking Bomyntra, you should:**

- Tell your doctor about all medications you are taking. Your doctor needs to know if you are taking other medications that also lower blood calcium levels
- Take good care of your teeth and gums and visit a dentist as recommended
- Tell your dentist that you are taking Bomyntra

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**Important Safety Information (continued)**

- Tell your doctor if you plan to have dental surgery or teeth removed
- Talk to your doctor before you stop taking Bomyntra about your risk for broken bones in your spine
- Women of child bearing age should use highly effective contraception while taking Bomyntra and for at least 5 months after the last dose of Bomyntra

**What are the possible side effects of Bomyntra?**
In patients with bone metastases from solid tumors receiving denosumab, the most common side effects were tiredness/weakness, low phosphate levels in your blood, and nausea. The most common serious side effect of denosumab was shortness of breath.

In patients with multiple myeloma receiving denosumab, the most common side effects were diarrhea, nausea, low red blood cells, low blood platelets and calcium levels, back pain, swelling of the lower legs or hands, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia.

The most common adverse reactions in patients with giant cell tumor of bone were joint pain, back pain, pain in arms and legs, musculoskeletal pain, tiredness, headache, nausea, common cold (runny nose or sore throat), toothache, vomiting, low phosphate levels in your blood, constipation, diarrhea, and cough. The most common serious adverse reactions were severe jaw bone problems (osteonecrosis), bone giant cell tumor, low red blood cells, pneumonia, and back pain.

The most common adverse reactions in patients with hypercalcemia of malignancy were nausea, shortness of breath, decreased appetite, headache, swelling of the lower legs or hands, vomiting, low red blood cells, constipation, and diarrhea. The most common serious adverse reactions of denosumab were fatigue and infection.

These are not all the possible side effects of Bomyntra. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

**Indications**

Bomyntra is a prescription medicine used for:

- Prevention fracture, spinal cord compression, or the need for radiation or surgery to bone 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.

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# Additional patient support and resources

**We are committed to being your partner by providing support and resources for your journey with BOMYNTRA® (denosumab-bnht).**

## To learn more

Scan the QR code or visit bomyntra.com for product information and dosing instructions.

**References: 1.** BOMYNTRA®. Prescribing information. Fresenius Kabi, LLC; 2025. **2.** Xgeva® Package insert. Amgen Inc; 2024. **3.** Bolster, MB. Osteoporosis. In: Merck Manual Consumer Version. Merck & Co., Inc.; 2023. https://www.merckmanuals.com/home/bone-joint-and-muscle-disorders/osteoporosis/osteoporosis. Accessed June 9, 2025. **4.** Declerck P, Danesi R, Petersel D, Jacobs I. The Language of Biosimilars: Clarification, Definitions, and Regulatory Aspects. Drugs. 2017 Apr;77(6):671-677. doi: 10.1007/s40265-017-0717-1. **5.** The U.S. Generic & Biosimilar Medicines Savings Report. September 2024. https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf. Accessed February 17, 2025.

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