



Your treatment journey with CONEXXENCE® (denosumab-bnht)



Important Safety Information

What is the most important information you should know about Conexxence (denosumab-bnht)?

If you receive Conexxence, you should not receive other denosumab products at the same time.

Conexxence can cause serious side effects including:

Increased risk of severe low calcium levels in your blood (hypocalcemia). Conexxence may lower the calcium levels in your blood. If you have low blood calcium before you start receiving Conexxence, it may get worse during treatment. Your low blood calcium must be treated before you receive Conexxence. Talk to your doctor before starting Conexxence. Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take Conexxence. Take calcium and vitamin D as your doctor tells you to.

See Important Safety Information throughout this brochure, and click to see [Full Prescribing Information](#), including the Medication Guide, which contains **Serious Side Effects** for CONEXXENCE® (denosumab-bnht).



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What is CONEXXENCE® (denosumab-bnht)?^{1,2}

CONEXXENCE® (denosumab-bnht) is an FDA-approved biosimilar to Prolia® (denosumab).

CONEXXENCE® is a medicine used for treatment:

- ▶ of postmenopausal women with osteoporosis at high risk for fracture
- ▶ to increase bone mass in men with osteoporosis at high risk for fracture
- ▶ of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- ▶ to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- ▶ to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Why do I need CONEXXENCE®?^{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.

CONEXXENCE® may help treat osteoporosis in postmenopausal women as well as men, including those at high risk for fracture, with glucocorticoid-induced osteoporosis, men receiving androgen deprivation therapy, and women receiving adjuvant aromatase inhibitor therapy.

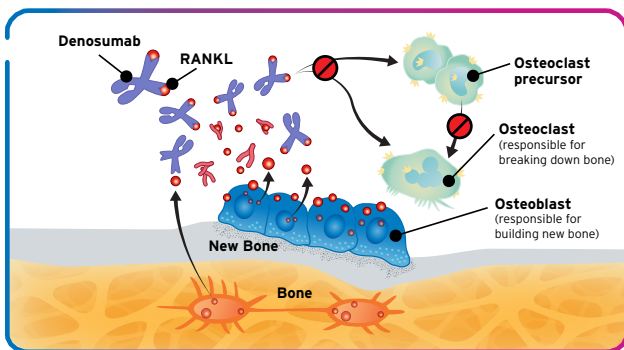
Important Safety Information (continued)

If you have advanced chronic kidney disease (may or may not be on kidney dialysis), Conexxence may increase your risk for severe low calcium levels in your blood, which could result in hospitalization, life-threatening events and death. A mineral and bone disorder associated with kidney disease called chronic kidney disease-mineral bone disorder (CKD-MBD) may increase your risk for severe low calcium levels in blood. Before you start Conexxence and during treatment, your doctor may need to do certain blood tests to check for CKD-MBD.

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How does CONEXXENCE® work?¹

CONEXXENCE® 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- κ B Ligand

Important Safety Information (continued)

Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- spasms, twitches, or cramps in your muscles
- numbness or tingling in your fingers, toes, or around your mouth

Serious allergic reactions have happened in people who take denosumab products. 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 your face, lips, or tongue; rash; itching; or hives.

Severe jaw bone problems (osteonecrosis) may happen when you take Conexxence. Your doctor should examine your mouth before you start Conexxence, and may tell you to see your dentist before you start Conexxence. It is important for you to practice good mouth care during treatment with Conexxence.

Unusual thigh bone fractures. Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture include new or unusual pain in your hip, groin, or thigh.





Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying Conexxence. Talk with your

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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 CONEXXENCE® (denosumab-bnht), and the reference (original) product, like Prolia® (denosumab). Biosimilars are safe and effective.

CONEXXENCE® and Prolia® 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 CONEXXENCE®, may be less expensive than reference (original) products, like Prolia®, which helps make critical medicines accessible to more patients.



On average, biosimilars frequently offer more than 40% price reductions compared with reference products⁵

Important Safety Information (continued)

doctor before starting Conexxence treatment. After your treatment with Conexxence is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Your risk for having more than 1 broken bone in your spine is increased if you have already had a broken bone in your spine. Do not stop, skip or delay taking Conexxence without first talking with your doctor. If your Conexxence treatment is stopped, talk to your doctor about other medicine that you can take.

Serious infections in your skin, lower stomach area (abdomen), bladder, or ear may happen if you take Conexxence. Inflammation of

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Conexxence®
denosumab-bnht

How do I take CONEXXENCE® (denosumab-bnht)?¹

Receive Your Injection Every 6 Months

Your healthcare provider will give you 60 mg of CONEXXENCE® 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 infusion center once every 6 months.

Helpful Reminders:



Take Calcium and Vitamin D Every Day

You may need to take calcium and vitamin D supplements (as needed) to help prevent or treat low blood calcium levels and keep your bones strong.



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.

Important Safety Information (continued)

the inner lining of the heart (endocarditis) due to an infection also may happen more often in people who take Conexxence. You may need to go to the hospital for treatment.

Conexxence is a medicine that may affect the ability of your body to fight infections. People who have a weakened immune system or take medicines that affect the immune system may have an increased risk for developing serious infections.

Skin problems such as inflammation of your skin (dermatitis), rash, and eczema may happen if you take Conexxence.

Bone, joint, or muscle pain. Some people who take denosumab products develop severe bone, joint, or muscle pain.

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Helpful Patient Resources

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

Understanding biologics and biosimilars

This brochure provides answers to frequently asked questions about biosimilars.



CONEXXENCE.com

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



Important Safety Information (continued)

Do not take Conexxence if you: have low blood calcium level; are pregnant or plan to become pregnant, as Conexxence may harm your unborn baby; or are allergic to denosumab products or any of the ingredients in Conexxence.

Before taking Conexxence, tell your doctor about all of your medical conditions, including if you:

- Take other denosumab products.
- Have low blood calcium.
- Cannot take daily calcium and vitamin D.
- Had parathyroid or thyroid surgery (glands located in your neck).
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome).
- Have kidney problems or are on kidney dialysis.
- Are taking medicine that can lower your blood calcium levels.
- Plan to have dental surgery or teeth removed.
- Are pregnant or plan to become pregnant.

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Important Safety Information (continued)

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with Conexxence.
- You should use an effective method of birth control (contraception) during treatment with Conexxence and for at least 5 months after your last dose of Conexxence.
- Tell your doctor right away if you become pregnant while taking Conexxence.

- Are breastfeeding or plan to breastfeed.

What are the possible side effects of Conexxence?

It is not known if the use of Conexxence over a long period of time may cause slow healing of broken bones. The most common side effects of Conexxence in women being treated for osteoporosis after menopause are back pain, pain in your arms and legs, high cholesterol, muscle pain, and bladder infection.

The most common side effects of Conexxence in men with osteoporosis are back pain, joint pain, and common cold (runny nose or sore throat).

The most common side effects of Conexxence in patients with glucocorticoid-induced osteoporosis are back pain, high blood pressure, lung infection (bronchitis), and headache.

The most common side effects of Conexxence in patients receiving certain treatments for prostate or breast cancer are joint pain, back pain, pain in your arms and legs, and muscle pain. Additionally, in denosumab-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

These are not all the possible side effects of Conexxence. 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

Conexxence (denosumab-bnht) is indicated for treatment:

- of postmenopausal women with osteoporosis at high risk for fracture
- to increase bone mass in men with osteoporosis at high risk for fracture
- of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
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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 CONEXXENCE® (denosumab-bnht).



To learn more

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



References: 1. CONEXXENCE®. Prescribing information. Fresenius Kabi, LLC; 2025. 2. Prolia® 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-Generics-Biosimilar-Medicines-Savings-Report.pdf>. Accessed February 17, 2025.

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