

When breast cancer spreads to your bones,

Take action
to prevent
devastating,
serious bone
problems*
with XGEVA®¹



Ask for the **#1 prescribed bone-targeting medicine**
proven superior[†] in preventing serious bone problems^{1,2}

*Serious bone problems are defined as broken bones (fractures), the need for bone surgery, radiation treatments for bone pain, and pressure on the spinal cord.¹

[†]Compared with zoledronic acid (ZA).¹

Indication

XGEVA® is a prescription medicine used to prevent 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.

IMPORTANT SAFETY INFORMATION

Do not take XGEVA® if you have low blood calcium (hypocalcemia). Your low blood calcium must be treated before you receive XGEVA®. XGEVA® 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.

Please see additional Important Safety Information on pages 12-13.

XGEVA®
(denosumab) injection
120 mg/1.7 mL vial



What are bone mets and how can they affect me?

Bone metastases (muh•TASS•tuh•seez), or bone mets, can pose a significant risk to the health of your bones³

Bone mets may be painful—but they aren't always. Regardless of whether you feel pain, bone mets can³⁻⁵:

- Disrupt the body's normal process that keeps bones strong
- Cause your bones to break down faster than normal
- Make bones weaker over time

When your bones weaken, you are at risk for serious bone problems. These are defined as^{1,6}:



Broken bones (fractures)



A need for surgery to prevent or repair broken bones



A need for radiation treatments to the bone



Pressure on the spinal cord (spinal cord compression)

There is never a good time to have a serious bone problem. Use this guide to learn about how common they are and what you can do to prevent them.

If I have bone mets, what is the likelihood that I will have a serious bone problem?

Without a proactive prevention plan in place, serious bone problems could occur sooner than you might think⁷

WITHIN 3 MONTHS
OF A BONE MET DIAGNOSIS



About **1 in 3** women suffered a serious bone problem⁷

Help protect yourself from serious bone problems by working with your doctor as soon as you've been diagnosed with a bone met

What is XGEVA[®] and what do I need to know?

IMPORTANT SAFETY INFORMATION (cont'd)

Do not take XGEVA[®] if you are allergic to denosumab or any of the ingredients of XGEVA[®]. Serious allergic reactions have happened in people who take XGEVA[®]. 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.

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Since 2010, nearly
1.5 million people with
cancer worldwide have
been treated with XGEVA[®]1,8

XGEVA[®] is a prescription medicine used to prevent fracture, spinal cord compression, or the need for radiation or surgery to bone in people with multiple myeloma and in people with bone mets from breast, prostate, lung cancer, and other solid tumors.¹

Important things to know about XGEVA[®]



Convenient shot given under the skin and does not involve infusion through the vein¹



Administered once every 4 weeks in your doctor's office¹



During treatment, you may be told to take vitamin D and calcium supplements to help prevent low calcium levels in the blood¹



Your doctor will check if you are pregnant before starting XGEVA[®]. Women should use highly effective birth control when taking XGEVA[®] and for at least 5 months after you stop taking it¹

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How much of a difference can XGEVA[®] make for me?

XGEVA[®] given every 4 weeks was compared with ZA in women with breast cancer and bone metastases¹

ZA, zoledronic acid.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information you should know about XGEVA[®]?

Do not take XGEVA[®] if you take Prolia. XGEVA[®] contains the same medicine as Prolia[®] (denosumab).

Severe jaw bone problems (osteonecrosis)

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

Please see additional Important Safety Information on pages 12-13.

XGEVA[®] was proven superior at preventing serious bone problems* for > 2 years^{1,9}



5 out of 10 of patients on ZA had not experienced a serious bone problem at 26.4 months.^⁹

For superior prevention of serious bone problems, ask your doctor for XGEVA[®]¹

*Serious bone problems are defined as broken bones (fractures), the need for bone surgery, radiation treatments for bone pain, and pressure on the spinal cord.¹

[†]In a clinical study comparing 1,026 patients on XGEVA[®] with 1,020 patients on ZA.^⁹

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Serious bone problems* can be painful¹⁰

XGEVA[®] given every 4 weeks was compared with ZA in women with breast cancer and bone metastases¹

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ZA, zoledronic acid.

IMPORTANT SAFETY INFORMATION (cont'd)

Unusual thigh bone fracture

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

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 XGEVA[®], that can be serious.

Please see additional Important Safety Information on pages 12-13.

Serious bone problems cause many women to feel pain¹⁰



More than **4 out of 5** women with a serious bone problem experienced bone pain¹⁰

XGEVA[®] does not treat pain; it is used to prevent serious bone problems.¹

In an analysis of time to worsening of pain in breast cancer,

Women taking XGEVA[®] went 3.9 months longer before experiencing moderate to severe pain than those taking ZA⁵



compared with 5.8 months with ZA

- A similar analysis done in patients with other tumor types and bone metastases did not find as much of a difference. In prostate cancer: XGEVA[®] 5.8 months vs ZA 4.9 months, which is a 0.9-month difference.¹¹ In solid tumor-only cancer: XGEVA[®] 4.7 months vs ZA 3.7 months, which is a 1-month difference¹²
- These values show how long it took for patients' pain to worsen
- The study was not designed to show a reduction in pain. It is not known if the difference between these two groups was due to either drug. Patients self-reported pain using a predetermined scale.⁵ Your results may vary. Please talk to your doctor about what these results may mean for you

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Give yourself the best chance of getting the superior results with XGEVA® seen in the clinical trials¹



Stay on track with XGEVA® using these tips:

- **Schedule** appointments for every 4 weeks in advance¹
- **Record** appointments in your calendar
- **Ask** family or friends for help getting to your doctor's office
- **Wear** loose fitting clothing to the injection to make it easier for the healthcare team member who will give the shot in your upper arm, upper thigh, or stomach area¹

If you missed a dose, talk to your doctor for help getting back on track with XGEVA®

ZA, zoledronic acid.

IMPORTANT SAFETY INFORMATION (cont'd)

Increased risk of broken bones in the spine after discontinuing XGEVA®

After your treatment with XGEVA® 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.

Please see additional Important Safety Information on pages 12-13.

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What resources are available to me?

If you and your doctor decide XGEVA® is right for you, Amgen Assist 360™ is here to help

Your Amgen Assist 360™ Nurse Ambassador* can help you find the resources† most important to you:

- Answer medication questions and help you sign up for injection reminders
- Refer you to resources for day-to-day living
- Help you understand your coverage and financial support options for any type of insurance, such as Amgen FIRST STEP™

Amgen FIRST STEP™ Program

If you are eligible‡ and commercially insured, the Amgen FIRST STEP™ Program can help you cover your out-of-pocket (OOP) prescription costs, including deductible, co-insurance, and co-payment.

- **\$0** OOP for first dose or cycle
- **\$5** OOP for subsequent doses or cycles, **up to the brand program benefit maximum**
- No income eligibility requirement



CALL TODAY

1-888-4ASSIST (1-888-427-7478)
Monday to Friday, 9AM to 8PM ET or
visit www.amgenassist360.com/enroll

*Amgen Nurse Ambassadors are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

†Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

‡Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal, state, or government-funded healthcare program. Not valid where prohibited by law.

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Support, Simplified

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Important Safety Information

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Do not take XGEVA® if you are allergic to denosumab or any of the ingredients of XGEVA®. Serious allergic reactions have happened in people who take XGEVA®. 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 XGEVA®?

Do not take XGEVA® if you take Prolia. XGEVA® contains the same medicine as Prolia® (denosumab).

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

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

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 XGEVA®, that can be serious.

Increased risk of broken bones in the spine after discontinuing XGEVA®
After your treatment with XGEVA® 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 XGEVA®. Tell your doctor right away if you are pregnant, plan to become pregnant, or suspect you are pregnant. XGEVA® can harm your unborn baby.

Tell your doctor if you:

- Are taking a medicine called Prolia® (denosumab) because it contains the same medicine as XGEVA®
- 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 XGEVA®, 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 XGEVA®
- Tell your doctor if you plan to have dental surgery or teeth removed
- Talk to your doctor before you stop taking XGEVA® about your risk for broken bones in your spine
- Women of child bearing age should use highly effective contraception while taking XGEVA® and for at least 5 months after the last dose of XGEVA®

What are the possible side effects of XGEVA®?

In patients with bone metastases from solid tumors using XGEVA®, the most common side effects were tiredness/weakness, low phosphate levels in your blood, and nausea. The most common serious side effect of XGEVA® was shortness of breath.

In multiple myeloma patients receiving XGEVA®, 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 in multiple myeloma patients was pneumonia.

These are not all the possible side effects of XGEVA®. For more information, ask your doctor or pharmacist.

Call your doctor 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.

Please see accompanying Prescribing Information.

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When breast cancer has spread to your bones,

Don't let unexpected bone problems disrupt your plans

Ask your doctor for XGEVA®

the **superior** bone-targeting medicine in preventing serious bone problems* (vs ZA)¹

Visit XGEVA.com to learn more

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IMPORTANT SAFETY INFORMATION (cont'd)

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Please see additional Important Safety Information on pages 12-13.

References: **1.** XGEVA® (denosumab) prescribing information, Amgen. **2.** Data on file, Amgen; 2019. **3.** Understanding advanced cancer, metastasis cancer, and bone metastases. American Cancer Society. Updated December 15, 2016. Accessed June 1, 2020. <https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/what-is.html>. **4.** Saad F, Eastham J. Zoledronic acid improves clinical outcomes when administered before onset of bone pain in patients with prostate cancer. *Urology*. 2010;76(5):1175-1181. **5.** Cleeland CS, Body J-J, Egerdie B, et al. Pain outcomes in patients with advanced breast cancer and bone metastases. *Cancer*. 2013;119(4):832-838. **6.** Managing symptoms of bone metastases. American Cancer Society. Updated December 16, 2016. Accessed June 1, 2020. <https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/managing-symptoms-of-bone-metastases.html>. **7.** Bhowmik D, Song X, Intorcchia M, Gray S, Shi N. Examination of burden of skeletal-related events in patients naive to denosumab and intravenous bisphosphonate therapy in bone metastases from solid tumors population. *Curr Med Res Opin*. 2019;35(3):513-523. **8.** Data on file, Amgen; 2020. **9.** Stopeck AT, Lipton A, Body J-J, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. *J Clin Oncol*. 2010;28(35):5132-5139. **10.** Kuchuk I, Hutton B, Moretto P, et al. Incidence, consequences and treatment of bone metastases in breast cancer patients experience from a single cancer centre. *J Bone Oncol*. 2013;2(4):137-144. **11.** Brown JE, Cleeland C, Fallowfield L, et al. Pain outcomes in patients with bone metastases from castrate-resistant prostate cancer: results from a phase 3 trial of denosumab vs zoledronic acid. Poster presented at: 26th Annual EAU Congress; March 18-22, 2011; Vienna, Austria. Abstract 1091. **12.** Henry D, Vadhan-Raj S, Hirsh V, et al. Delaying skeletal-related events in a randomized phase 3 study of denosumab versus zoledronic acid in patients with advanced cancer: an analysis of data from patients with solid tumors. *Support Care Cancer*. 2014;22:679-687.

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