Help prevent serious bone problems

That are fracture, spinal cord compression, radiation or surgery to the bone



You may have several questions about your cancer, and wonder why bone health is now an important part of your treatment. When cancer spreads to the bone, it can make bone break down, which can lead to painful fractures and other problems that are the need for bone surgery, radiation treatments for bone pain, and pressure on the spinal cord.³

XGEVA® is a prescription medicine approved by the FDA for the prevention of serious bone problems when cancer (solid tumors) has spread to the bones. It is given as 1 shot every 4 weeks and does not involve the use of an infusion through a vein.¹

Talk to your doctor to see if XGEVA® may be right for you. Individual results may vary.

This brochure helps explain your condition, your treatment with XGEVA®, dosing information, and some possible side effects to be aware of. It also provides reimbursement services information for help with your XGEVA® co-pay.

Important Safety Information

Do not take XGEVA® if you have low blood calcium (hypocalcemia) or are allergic to denosumab or any of its ingredients. XGEVA® can significantly lower the calcium levels in your blood and some deaths have been reported. Severe jaw bone problems and unusual thigh bone fracture have been reported. You should not become pregnant while taking XGEVA® because XGEVA® can harm your unborn baby.

Please see additional Important Safety Information on pages 14-15.

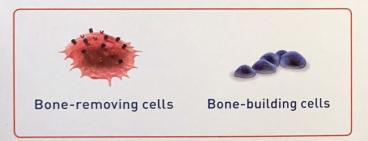


Why do serious bone problems matter?

Cancer cells from the primary (original) tumor may travel through the bloodstream or lymphatic system. Cancer that spreads to other parts of the body may frequently spread to bone. When these cells grow in the bone, they are called bone metastases (muh·TASS·tuh·seez).³



There are cells in your body that remove old bone, and other cells that rebuild new bone. This ongoing process is part of what keeps your bones strong.⁴



In bone with metastases, bone-building cells send a signal that causes bone-removing cells to be overactive.^{1,4}

This can leave you with weaker bones and can cause a fracture or another serious bone problem. Other serious bone problems include surgery to repair or prevent broken bones, radiation to relieve bone pain, and pressure on the spinal cord (spinal cord compression).^{1,3}

How does XGEVA® work?

XGEVA® can help prevent serious bone problems

XGEVA® (ex·JEE·va) is a prescription medicine approved to prevent these serious bone problems. XGEVA® is prescribed to people with bone metastases from breast cancer, prostate cancer, lung cancer, and other types of solid tumors.¹

XGEVA® is not used to prevent serious bone problems in patients with multiple myeloma.¹

XGEVA® works by blocking the key signal that causes bone metastases to break down bone, which can lead to serious bone problems such as fracture.¹

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How will I receive XGEVA®?

XGEVA® is a **convenient shot** given **every 4 weeks**. It is a shot under the skin (subcutaneous) and does not involve an infusion through a vein (intravenous)¹

- XGEVA® will be injected into your upper arm, upper thigh, or abdomen¹
- It's important to take XGEVA® at the recommended dosing schedule
- It may help to schedule future appointments in advance

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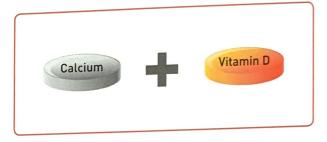
Do not take XGEVA® if you are allergic to denosumab or any of the ingredients of XGEVA®. Serious allergic reactions have happened in people who take XGEVA®. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction.



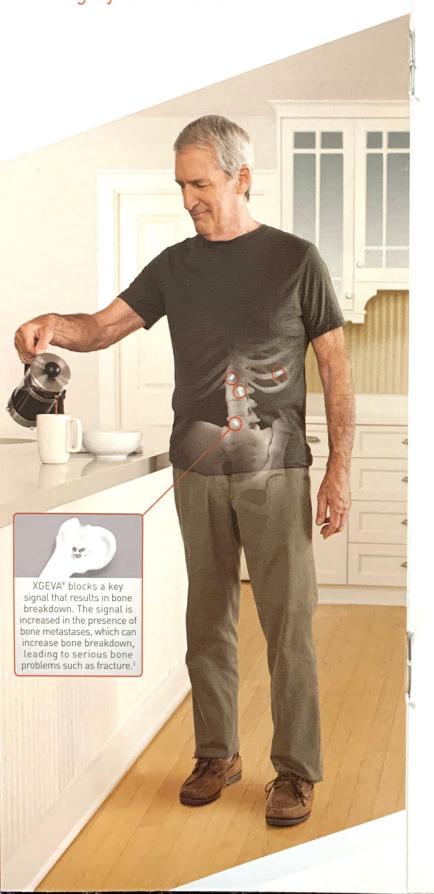
Calcium and vitamin D should be taken as prescribed by your doctor while you take XGEVA®1

Do not take XGEVA® if you have low blood calcium (hypocalcemia [hy•poh•kal•SEE•mee•uh]).1

Because medicines like XGEVA® help prevent bone breakdown, they reduce the release of calcium from bone into the blood. This can lead to potentially serious low levels of calcium in your blood, known as hypocalcemia.^{1,5}



If you have prostate cancer and bone metastases, you are at risk of serious bone problems that are fracture, spinal cord compression, radiation or surgery to the bone¹



In a study of 1,901 men with prostate cancer, XGEVA® was shown to be better than zoledronic acid in preventing serious bone problems¹

Men with prostate cancer had an

18% lower chance of serious bone problems with XGEVA® than men receiving zoledronic acid, one study found.1

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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.

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®?
XGEVA® contains the same medicine as Prolia® (denosumab). If you are taking XGEVA® do not take Prolia®.

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 metastases, 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.

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. 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®.

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
- Are pregnant, plan to become pregnant, suspect you are pregnant, or breastfeeding

While taking XGEVA®, you should:

- 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
- 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®? The most common side effects in patients receiving XGEVA® for the prevention of serious bone problems were tiredness/weakness, low phosphate levels in your blood, and nausea. The most common serious side effect of XGEVA® was shortness of breath.

The most common side effects in patients receiving XGEVA® for giant cell tumor of bone were joint pain, headache, nausea, tiredness, back pain, and extremity pain. The most common serious side effects were severe jaw bone problems and swelling or infection of the bone.

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.



What are some available resources?

XGEVA® is covered by almost all insurers nationwide. 7.8

Your insurer, including Medicare, may cover XGEVA® at no additional cost to you.

Approximately 70% of XGEVA® patients may expect to have no out-of-pocket costs.9*

*Estimated amount of Medicare beneficiaries with supplemental coverage and commercially insured patients with no out-of-pocket cost; based on XGEVA® payor mix and coverage of XGEVA® and other similar products. Does not include costs related to office visit, physician, staff, or administrative charges associated with administering XGEVA®.

For more information about your out-of-pocket costs for XGEVA® and available patient assistance programs, speak to your oncology office staff or contact Amgen Assist® at 1-888-4ASSIST [1-888-427-7478].

Multiple options are available for help with financial assistance.

The XGEVA FIRST STEP™ Program is a co-pay coupon program for eligible[†] commercially insured patients.

- No income requirements
- \$25 out-of-pocket per dose
- Up to \$5,000 per 6-month period[‡]
- Program covers out-of-pocket XGEVA® costs only
 - Program does not cover office visit, physician, staff, or administrative charges associated with administering XGEVA®



- Medicare patients may be eligible for financial assistance from independent co-pay foundations
- Uninsured patients may qualify to receive XGEVA® at no cost from the Safety Net Foundation®

The Amgen FIRST STEP™ Program MasterCard is issued by The Bancorp Bank pursuant to license by MasterCard International, and this card may not be used everywhere Debit MasterCard is accepted. No cash or ATM access. MasterCard is a registered trademark of MasterCard International Incorporated. The Bancorp Bank; Member FDIC.

- Must have private commercial health insurance that covers medication costs for XGEVA® (denosumab) under a medical benefit plan
- May not be a participant in any federal, state, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TriCare
 Program invalid where otherwise prohibited by law
- *Total program benefits \$5,000 per patient per 6-month calendar period. Patient is responsible for costs above this amount. Patients may not seek reimbursement for value received from the XGEVA FIRST STEP™ Program from any third-party payers, including a flexible spending account or healthcare savings accounts. If at any time patients begin receiving coverage under any federal, state, or government-funded healthcare program, patients will no longer be eligible to participate in the Amgen FIRST STEP™ Program and must call 1-888-65-STEP1 (1-888-657-8371) Monday through Friday, 9 AM-8 PM ET to stop participation. Restrictions may apply. Offer subject to change or discontinuation without notice. This is not health insurance. For a complete list of eligibility requirements, call 1-888-657-8371.