

Bone metastases, or what you might know as bone mets, are cancer that has spread to the bones, which can lead to serious bone problems.<sup>1,\*</sup>

\*Serious bone problems are defined as broken bones (fractures), the need for surgery to bones, the need for radiation treatments to the bone, and spinal cord compression.<sup>1</sup>

**Here are questions you can ask a member of your care team:**

## Step 1- Know your risk:

What is my risk for a serious bone problem?  
What happens if I suffer a serious bone problem?

## Step 2- Care for your bones:

Should I be on medication to reduce the risk of a serious bone problem?  
Could XGEVA<sup>®</sup> be right for me to prevent serious bone problems?

## Step 3- Ask about XGEVA<sup>®</sup>:

How is XGEVA<sup>®</sup> administered?  
What potential side effects should I know about?

## 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.

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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®?

**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.



## Important Safety Information (continued)

### 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.

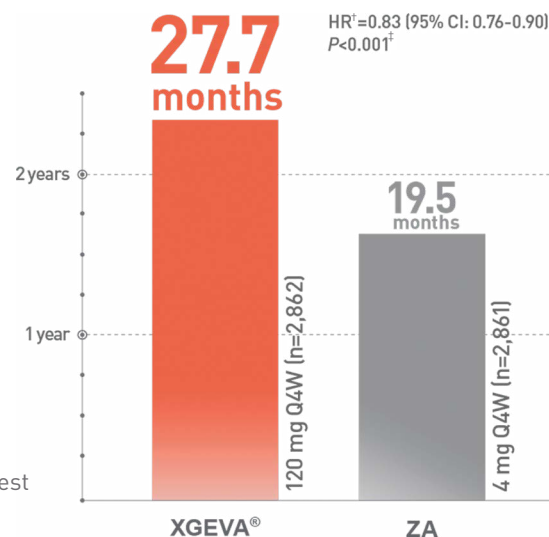
These are not all the possible side effects of XGEVA®. For more information, ask your doctor or pharmacist.

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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please see [Prescribing Information](#).



In studies, that compared time to first serious bone problems\* of patients whose cancer from solid tumors has spread to the bone, half of patients on XGEVA® were still free from a serious bone problem at 27.7 months compared to 19.5 months for those on zoledronic acid. Total number of patients was 5,723.<sup>2</sup>



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<sup>†</sup>Hazard ratio (HR) is defined as the increase or decrease in likelihood of an event of interest (in this case, serious bone problems) for one group relative to a comparator group.<sup>2</sup>

<sup>‡</sup>p value for superiority.<sup>2</sup>

## Have you been prescribed XGEVA®? Here is what **you** can do

### What am I responsible to pay?

The Amgen® SupportPlus Co-Pay Program may help patients with private or commercial insurance lower their out-of-pocket costs

- Pay as little as \$0<sup>§</sup> out-of-pocket for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment<sup>§</sup>
- No income eligibility requirement

If you don't have private or commercial insurance (eg, self-purchased or through an employer), Amgen SupportPlus can provide information about independent nonprofit foundations that may be able to help.<sup>\*\*</sup>

### Who else can I talk to about XGEVA®?

Dedicated Amgen Nurse Partners<sup>††</sup> will be with you along the way to offer supplemental support and provide information about resources to help you access your prescribed Amgen medication.

**CALL 866-264-2778 Monday to Friday, 9:00 am to 8:00 pm ET, or visit [www.AmgenSupportPlus.com](http://www.AmgenSupportPlus.com)**

<sup>§</sup>Eligibility criteria and program maximums apply. See [AmgenSupportPlus.com/Copay](http://AmgenSupportPlus.com/Copay) for full Terms and Conditions.

<sup>\*\*</sup>Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

<sup>††</sup>Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your treatment team and do not provide medical advice, nursing, or case-management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

### References:

1. Stopeck AT, Fizazi K, Body JJ, et al. Safety of long-term denosumab therapy: results from the open label extension phase of two phase 3 studies in patients with metastatic breast and prostate cancer [published correction appears in *Support Care Cancer*. 2015 Oct 19;:]. *Support Care Cancer*. 2016;24(1):447-455.
2. Lipton A, Fizazi K, Stopeck AT, et al. Superiority of denosumab to zoledronic acid for prevention of skeletal-related events: a combined analysis of 3 pivotal, randomised, phase 3 trials. *Eur J Cancer*. 2012;48(16):3082-3092.

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

**AMGEN®**

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