

For patients with cancer and bone metastases from solid tumors

Your doctor has prescribed XGEVA® to help prevent bone complications that are fractures, spinal cord compression, the need for radiation, or surgery to bone

Do not take XGEVA® if you have low blood calcium (hypocalcemia).

- XGEVA® can significantly lower the calcium levels in your blood and some deaths have been reported. Your low blood calcium must be treated before you receive XGEVA®.

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®.

Take at least:

Your doctor typically recommends that you take daily:



Or at a dose of: _____ mg _____ IU

Call your doctor if you experience any of these symptoms of hypocalcemia:

- Spasms, twitches, cramps, or stiffness in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Also, tell your doctor if you:

- 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

XGEVA®
(denosumab)

Subcutaneous injection.

Read the Important Safety Information on the reverse for additional safety considerations while taking XGEVA®.

R_x*

For: _____ Date: _____

*Daily: at least Calcium 500 mg
& Vitamin D 400 IU*

Or at a dose of: Calcium _____ mg Vitamin D _____ IU

*This illustration is for reminder purposes only.

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.

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 other products containing denosumab (for example, Prolia). XGEVA® should not be taken with other products containing 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 any other medicine containing denosumab (for example, Prolia)
- 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- FDA1088.

Please see accompanying Prescribing Information.

AMGEN

Oncology

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
USA-162X-81551 04/25

XGEVA®
(denosumab)