

Denosumab (Xgeva)

About This Medicine

Denosumab (Xgeva) is used to prevent and treat bone problems due to bone metastasis from cancer. It is also used to treat high calcium levels due to cancer. It is given as an injection under your skin (subcutaneously).

Possible Side Effects

- Decrease in red blood cells and platelets. This may make you feel more tired and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move your bowels)
- · Tiredness and weakness
- Swelling of the hands, feet, or any other part of the body
- Decreased appetite (decreased hunger)
- Electrolyte changes
- Back pain or pain in arms or legs
- Pain in the joints
- Headache
- · Upper respiratory tract infection
- Trouble breathing
- Rash

Note: Each of the side effects above was reported in 10% or greater of patients treated with denosumab (Xgeva). All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of
allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are
swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is



beating in a fast or not normal way. If this happens, do not take another dose of this medicine. You should get urgent medical treatment.

- Severe low calcium, during and after treatment, which can be life-threatening.
- Osteonecrosis of the jaw. This is a breakdown of the jawbone. It is a serious but rare health problem.
- · Risk of femoral bone fractures
- High levels of calcium once treatment is complete in patients with certain conditions
- Risk of vertebral (spinal) fractures when treatment is stopped, especially if you have a history of fractures or osteoporosis. Do not stop treatment without first talking to your doctor.

Important Information

- Take calcium and vitamin D supplements as your doctor recommends to decrease your risk of low calcium.
- Do not stop, skip or delay taking denosumab (Xgeva) without first talking with your doctor, as this can increase your risk of breaking bones.
- Do not substitute or take at the same time as Prolia, which is another brand of denosumab.

Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop constipation and/or diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- Manage tiredness by pacing your activities for the day. Be sure to include periods of rest between energy-draining activities.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.



- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Tell your dentist and/or oral surgeon that you are taking this medicine. You should not have major
 dental surgery while on this medicine. Talk to your doctor about any dental problems you may have
 before starting this medicine. You may need to see your dentist to have a dental exam and fix any
 dental problems before starting this medicine. Take good care of your teeth. Make sure you see
 your dentist for regular follow-up appointments.

Food and Medicine Interactions

- There are no known interactions of denosumab (Xgeva) with food.
- This medicine may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- · Headache that does not go away
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Wheezing and/or trouble breathing
- Coughing up yellow, green, or bloody mucus
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. If this happens, call 911 for emergency care.
- Signs of osteonecrosis of the jaw: pain, swelling or infection of the gums, loose teeth, poor healing of the gums, numbness, or the feeling that your jaw is heavy
- Signs of low calcium: numbness or tingling around your mouth or in your hands or feet, muscle stiffness, twitching, spasms, or cramps
- Signs of high calcium: Increased thirst, increased urine, pain in your abdomen, nausea and/or vomiting (throwing up), muscle pain, twitching, or weakness



- Pain that does not go away, or is not relieved by prescribed medicines
- New hip, thigh or groin pain, or other unexplained bone pain
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning**: This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your treatment and for at least 5 months after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- Breastfeeding warning: It is not known if this medicine passes into breast milk. For this reason,
 women should not breastfeed during treatment because this medicine could enter the breast milk
 and cause harm to a breastfeeding baby. Women should talk to their doctor about the appropriate
 timing to start breastfeeding after treatment.
- Fertility warning: Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children.

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