

## Denosumab (Xgeva)

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### About This Drug

Denosumab 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. This may make you feel more tired.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move your bowels)
- Tiredness and weakness
- Decreased appetite (decreased hunger)
- Electrolyte changes
- Back pain
- Headache
- Trouble breathing
- Swelling of your legs, ankles and/or feet

**Note:** Each of the side effects above was reported in 20% or greater of patients treated with denosumab. Not all possible side effects are included above.

### Warnings and Precautions

- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug 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 drug. You should get urgent medical treatment.**
- Severe low calcium, during and after treatment, which can be life-threatening. You may experience numbness or tingling around your mouth or in your hands or feet. Other symptoms of low calcium are muscle stiffness, twitching, spasms, or cramps.
- 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 growing skeletons
- Risk of broken bones 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 substitute or take at the same time Prolia, which is another brand of denosumab.

## Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, 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 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Tell your cancer doctor if you have any problems with your teeth or jaw before you start this drug. It is important that your dentist knows that you are on this drug. Give your dentist and your cancer doctor each other's name and phone number so they may call each other if they have any questions.
- Brush and floss your teeth as directed.

## Food and Drug Interactions

- There are no known interactions of denosumab with food.
- This drug 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
- Chills
- Headache that does not go away
- Wheezing or trouble breathing
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Pain that does not go away, or is not relieved by prescribed medicines
- 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)
- 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 such as 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 such as numbness or tingling around your mouth or in your hands or feet. Other symptoms of low calcium are muscle stiffness, twitching, spasms, or cramps.
- New hip, thigh or groin pain, or other unexplained bone pain
- If you think you may be pregnant

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 5 months after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment because this drug 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:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children.



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