

Denosumab

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You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

Pronunciation

(den OH sue mab)

Warning

Prolia, Bilyos, Bosaya, Conexxence, Enovy, Jubbonti, Ospomyv, Osvyrti, and Stoboclo:

- This drug may lower blood calcium levels. If you already have low blood calcium, it may get worse. Low blood calcium must be treated before getting this drug.
- People who have some types of kidney problems have a higher risk of very low calcium levels. This includes people who are on dialysis. Sometimes, very low calcium levels have needed treatment in a hospital and have been life-threatening or deadly. A certain health problem called chronic kidney disease-mineral bone disorder (CKD-MBD) may raise the risk of very low calcium levels. Your doctor may test you for CKD-MBD before starting this drug and while you take it.

What is this drug used for?

- It is used to treat soft, brittle bones (osteoporosis).
- It is used for bone growth.
- It is used when treating some cancers.
- It is used to treat bone loss in patients getting certain treatments for cancer.

- It is used to treat high calcium levels in patients with cancer.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have low calcium levels.
- If you are using another drug that has the same drug in it.
- If you are pregnant or may be pregnant. Some brands of this drug are not for use during pregnancy.
- If you are breast-feeding or plan to breast-feed.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- This drug may raise the chance of a broken leg. Talk with the doctor.
- If treatment with this drug is stopped, skipped, or delayed, the chance of a broken bone is raised. This includes bones in the spine.

The chance of having more than 1 broken bone in the spine is raised if you have ever had a broken bone in your spine. Do not stop, skip, or delay treatment with this drug without talking to your doctor.

- Have your blood work and bone density checked as you have been told by your doctor.
- Take calcium and vitamin D as you were told by your doctor.
- Have a dental exam before starting this drug.
- Take good care of your teeth. See a dentist often.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, use birth control while taking this drug and for 5 months after your last dose. If you get pregnant, call your doctor right away.

Xgeva, Aukelso, Bilprevda, Bomynta, Jubereq, Osenvelt, Wyost, Xbryk, and Xtrenbo:

- Very low blood calcium levels have happened with this drug. Sometimes, this has been deadly. If you have questions, talk with the doctor.
- High calcium levels have happened after this drug was stopped in people whose bones were still growing and people with giant cell bone tumor. Call your doctor right away if you have signs of high calcium levels like weakness, confusion, feeling tired, headache, upset stomach or throwing up, constipation, or bone pain.

Prolia, Bilydos, Bosaya, Conexxence, Enovy, Jubbonti, Ospomyv, Osvyrti, and Stoboclo:

- Very bad infections have been reported with use of this drug. If you have any infection, are taking antibiotics now or in the recent past, or have many infections, talk with your doctor.
- High cholesterol has happened with this drug. If you have questions, talk with the doctor.
- This drug is not approved for use in children. High calcium levels have

been reported in some children, which sometimes needed to be treated in the hospital. Bone and teeth growth may also be affected. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

All products:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
 - Signs of low calcium levels like muscle cramps or spasms, numbness and tingling, or seizures.
 - Confusion.
 - Mouth sores.
 - Swelling in the arms or legs.
 - Feeling very tired or weak.
 - Any new or strange groin, hip, or thigh pain.
 - Very bad bone, joint, or muscle pain.
 - Shortness of breath.
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- This drug may cause jawbone problems. The risk may be higher with longer use, cancer, dental problems, ill-fitting dentures, anemia, blood clotting problems, or infection. It may also be higher if you

have dental work, chemo, radiation, or take other drugs that may cause jawbone problems. Many drugs can do this. Talk with your doctor if any of these apply to you, or if you have questions. Call your doctor right away if you have jaw swelling or pain.

Xgeva, Aukelso, Bilprevda, Bomynta, Jubereq, Osenvelt, Wyost, Xbryk, and Xtrenbo:

- Signs of low phosphate levels like change in eyesight, feeling confused, mood changes, muscle pain or weakness, shortness of breath or other breathing problems, or trouble swallowing.
- Severe dizziness or passing out.
- Any unexplained bruising or bleeding.

Prolia, Bilydos, Bosaya, Conexxence, Enoby, Jubbonti, Ospomyv, Osvyrti, and Stoboclo:

- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
 - Signs of skin infection like oozing, heat, swelling, redness, or pain.
 - Signs of high or low blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
 - Chest pain.
 - Abnormal heartbeat.
 - Small bumps or patches on your skin, dry skin, or if your skin feels like leather.
 - Bladder pain or pain when passing urine or change in how much urine is passed.
 - Passing urine more often.
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- Rarely, a pancreas problem (pancreatitis) has happened with this drug. This has included 1 death. Call your doctor right away if you have signs of pancreatitis like very bad stomach pain, very bad back

pain, or very bad upset stomach or throwing up.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects.

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?

- If you need to store this drug at home, check the box or the leaflet that comes in the box to see how to store it. If you have questions about how to store this drug, talk with the pharmacist.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer: This generalized information is a limited summary of diagnosis, treatment, and/or medication

information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based