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Denosumab: Patient drug information

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(For additional information <u>see "Denosumab: Drug information"</u> and <u>see "Denosumab: Pediatric drug information"</u>)

Brand Names: US Prolia; Xgeva

Brand Names: Canada Prolia; Xgeva

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 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 have an allergy to denosumab or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- · If you have low calcium levels.
- If you are breast-feeding or plan to breast-feed.
- If you are pregnant or may be pregnant. Some brands of this drug are not for use during pregnancy.
 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.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Have a bone density test as you have been told by your doctor. Talk with 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.
- · If you smoke, talk with your doctor.
- If you are a man and your sex partner is pregnant or gets pregnant at any time while you are being treated, talk with your doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.

Xgeva®:

- Use birth control you can trust to prevent pregnancy while you are taking this drug and for 5 months after you stop taking it.
- If you get pregnant while taking this drug or within 5 months after your last dose, call your doctor right away.

Prolia™:

- 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.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- This drug may lower blood calcium levels. If you already have low blood calcium, it may get worse
 with this drug. Sometimes, blood calcium levels have stayed low for weeks or months after use of this
 drug. Talk with the doctor.
- After this drug is stopped, 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 treatment with this drug without talking to your doctor.
- Use birth control that you can trust to prevent pregnancy while taking this drug.
- If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

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 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.
- · 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.
- This drug may cause jawbone problems. The chance may be higher the longer you take this drug. The chance may be higher if you have cancer, dental problems, dentures that do not fit well, anemia, blood clotting problems, or an infection. The chance may also be higher if you are having dental work, getting chemo or radiation, or taking other drugs that may cause jawbone problems like some steroid drugs. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure. Call your doctor right away if you have jaw swelling or pain.

Xgeva®:

- Muscle pain or weakness.
- Seizures.
- · Shortness of breath.
- High calcium levels have happened after this drug was stopped in people whose bones were still
 growing. 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™:

- 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 a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- · Chest pain.
- · A heartbeat that does not feel normal.
- Very bad skin irritation.
- Bladder pain or pain when passing urine or change in how much urine is passed.
- · Passing urine more often.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

All products:

· Back pain.

Xgeva®:

- · Hard stools (constipation).
- · Not hungry.
- Joint pain.
- · Feeling tired or weak.
- · Headache.
- Upset stomach or throwing up.
- Loose stools (diarrhea).

<u>Prolia™:</u>

Muscle or joint pain.

- · Sore throat.
- · Runny nose.
- · Pain in arms or legs.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

• It is given as a shot into the fatty part of the skin.

What do I do if I miss a dose?

· 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, talk with your doctor, nurse, or pharmacist about how to store it.

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 a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.
- 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.

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