Denosumab (Xgeva, Prolia)

What is Denosumab (den-OSE-ue-mab) and how does it work?
Denosumab is a type of targeted cancer therapy called a “monoclonal antibody”. Denosumab targets certain bone destroying cells called, “osteoclasts”, and stops them from weakening the bone any further. Denosumab is used to prevent bone breaks (fractures), relieve pain and make bones stronger in patients whose cancer has spread to the bone. Denosumab is also used to treat osteoporosis (thinning of the bones) in women who have gone through menopause and have an increased risk for bone fractures.

What should I tell my doctor before starting Denosumab?
Talk to your doctor about the following:

- If you have very low calcium in your blood (hypocalcemia).
- If you have gum or dental problems, dentures that do not fit very well, or if you have had any mouth surgery.
- If you are pregnant or think you may be pregnant. Your doctor will talk to you about birth control while getting Denosumab.
- If you are breastfeeding.
- If you are allergic to latex.

How will my treatment be given?
This medicine is given by an injection just under your skin using a very small needle. The injection will be given in your upper arm, upper thigh, or stomach. You will have to go to your doctor’s office or a clinic for this injection.
If you have cancer and the disease has spread to your bones, you will get an injection of Denosumab every 28 days. If you are a female who has gone through menopause and you are receiving Denosumab to treat osteoporosis, you will get an injection of Denosumab every 6 months.

**What are the side effects of this medicine?**

Every person responds differently to treatment. Some of the more common side effects are:

- Fever, chills, headache, weakness, bone pain, muscle and joint aches on the day that you get your injection (these side effects usually go away within a few days and decrease with each dose)
- Mild stomach upset or stomach pain
- Heartburn, gas or diarrhea
- Mild back pain or joint pain
- Fatigue
- Skin rash
- Cough or difficulty breathing
- Redness, pain, itching, burning, swelling, or a lump under the skin where the shot was given

**Is there anything else I should know about this treatment?**

- Denosumab can cause low levels of calcium in your blood. Call your doctor if you have any of the following signs: muscle spasms, twitching, or numbness or tingling in your fingers, toes, or around your mouth.
- Patients taking Denosumab need a certain amount of calcium and vitamin D each day. Your doctor, nurse or pharmacist will talk with you about the amount you will need to take.
- Do not get pregnant or breastfeed while taking this medicine. Tell your doctor right away if you become pregnant.
- Call your doctor or dentist if you are having any of the following problems:
  - Pain, swelling or numbness in the mouth or jaw
- A heavy feeling in the jaw
- Loose teeth
- Any other problems with your teeth or jaw

- Be sure to tell all of your doctors, if you are having dental procedures while receiving Denosumab.

**What is “Osteonecrosis of the Jaws” (ONJ)?**

ONJ is a condition that some people develop while taking Denosumab. ONJ causes ulcers (non-healing wounds) to form on the gum and often on the jaw. If this happens your doctor will give you medicine for pain and to fight infection. The risk of developing ONJ while receiving Denosumab is extremely rare.

**What kind of treatment is available for ONJ?**

To help the ulcers heal properly, your doctor may prescribe antiseptic mouth rinses, antibiotics, or removal of dead bone from the affected area. If you develop ONJ, your doctor or dentist may send you to a specialist in oral medicine to decide on the best treatment for you.

**What can I do to avoid ONJ?**

Unless your doctor decides that you need to start treatment right away, you should have a dental exam before you receive your first dose of Denosumab. Preventive dental care may reduce the chances of developing ONJ. Some patients may need to have teeth removed or other dental work completed before starting treatment. If this needed, your doctor will allow plenty of time for your mouth to heal before starting Denosumab.

Assistance may be available if you cannot pay for a dental exam due to a lack of insurance. Tell your doctor if you would like information about these resources.

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