

Medication Information Sheet

denosumab (den-OH-sue-mab)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Xgeva®

Appearance: clear, colourless to slightly yellowish solution

What is this medication for?

Denosumab may:

- Help relieve bone pain and prevent broken bones in some types of cancer that arise from or spread to the bones
- Be used to treat giant cell tumour of bone in some patients
- Be used to remove excess calcium in the blood that is a problem with some types of cancer, if other treatments have not worked

What should I do before I have this medication?

- Tell your doctor and pharmacist if you have or had:
 - dental or kidney problems,
 - have any planned dental work,
 - take other medications for bone problems,
 - or have any allergies.
- Do not use Xgeva® with Prolia®, as both medications contain denosumab.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding.
- If there is ANY chance that you or your partner may become pregnant, you and your partner together must:
- ► Use 2 effective forms of birth control at the same time while taking this drug. Do not take birth control pills if you have breast cancer. Keep using birth control until at least **5 months** after the last dose. Discuss with your healthcare team.

- Do not breastfeed while taking this drug.

How is this medication given?

- This drug is given by injection under the skin, in the upper arm, upper thigh, or the abdomen.
- If your health care provider will be injecting the drug for you, ask about the drugs and supplies you will need to bring for your next visit.

What else do I need to know while on this medication?

- Although it is unlikely that other medications can affect your treatment, make sure your health care team knows about all of your medicines (prescription or over-the-counter medications, herbals and supplements). Check with your health care team before starting or stopping any of them.
- To prevent your blood calcium level from going down while using this drug, your doctor may tell you to take calcium and vitamin D supplements. Do not take calcium or vitamin D if you have or had high calcium levels in the blood. Talk to your health care team before taking these supplements.
- **For mild aches and pain or fever:**
 - ◊ If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
 - ◊ You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - ◊ Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
 - ◊ **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.
- Do not stop using this drug without speaking to your doctor. There may be a higher risk of having broken bones in the spine after treatment ends, especially in people who have had bone thinning or broken bones.

How should I safely store this medication?

- Keep in the refrigerator, but do not freeze. Keep out of sight and reach of children and pets.

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Before use, the drug vial (in its original container) can be brought to room temperature (usually takes 15-30 minutes). Once the drug is removed from the refrigerator, it must be kept at room temperature (up to 25°C) and used within 30 days. Do not warm the drug by other methods.
- If you are receiving the injection at home, proper disposal of drug vials, needle covers, needles and syringes are very important. They should never be reused. These must always be disposed in a puncture-proof container. Ask your pharmacist for help on how to properly dispose of these items, including the filled container.

What are the side effects of this medication?

The following side effects have been seen in people using denosumab with other chemotherapy drugs, so some of these effects may also be related to chemotherapy.

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>Nausea and vomiting (generally mild)</p> <p>May occur in hours to days after your treatment.</p> <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. <p>Also see Nausea & Vomiting pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p>Anemia (low red blood cells)</p> <ul style="list-style-type: none"> • You may feel more tired or weak than normal and have pale skin. • This may occur in days to weeks after you start or receive your medication. • Rest often and eat well. • Light exercise, such as walking may help. • You may need medication or a blood transfusion. • If it is very bad, your doctor may ask you to stop the medication that is causing the low red blood cells. 	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>Fatigue (tiredness)</p> <ul style="list-style-type: none"> • Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). • Avoid driving or using machinery if you are feeling tired <p>See our Fatigue pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p>Mild joint, muscle pain or cramps (common); headache (less common)</p> <ul style="list-style-type: none"> • Take your pain medication as prescribed by your doctor. • You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. • Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. • Rest often and try light exercise as it may help. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>Low appetite</p> <ul style="list-style-type: none"> • You may not feel like eating or you may lose weight. • Try to eat foods that you like and eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have a low appetite. • See our Loss of appetite pamphlet for more information. 	Contact your health care team if no improvement or if severe
<p>Constipation</p> <p>To help prevent constipation :</p> <ul style="list-style-type: none"> • Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. • Be Active. Exercise can help to keep you regular. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<ul style="list-style-type: none"> • Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation :</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do. <p>See the Constipation Pamphlet for more information.</p>	
<p>Cough; feeling short of breath</p> <p>You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose.</p> <p>If you have chest pain, difficulty breathing or cough up blood, get emergency medical help right away.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p>Diarrhea</p> <p>May happen days to weeks after you get your treatment.</p> <p>If you have diarrhea :</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it. • Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. <p>See the Diarrhea pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p>Salt imbalances (may be severe)</p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p> <p>Rarely, some patients with giant cell tumour of the bone or with growing bones have developed high calcium levels in the blood, weeks to months after denosumab treatment ends. Your doctor may monitor your calcium levels after you stop treatment.</p>	<p>Get emergency medical help right away</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>Flu-like symptoms</p> <ul style="list-style-type: none"> You may have fever, chills and muscle pain without any signs of infection, such as a sore throat, cough or skin rash. It may happen at any time after you receive your treatment and it usually goes away as your body gets used to the medication. Contact your health care team if these feelings bother you. Check your temperature to make sure you don't have a fever. If you do not have a fever, you may take acetaminophen (Tylenol®) tablets to help you feel better. Ask your health care team for the correct dose for you. If you do have a fever, speak to your health care team or go to the nearest emergency room. 	Contact your health care team if no improvement or if severe
<p>Pains or cramps in the belly</p> <ul style="list-style-type: none"> If you have constipation or diarrhea it may be causing the pain in your belly. If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	Contact your health care team if no improvement or if severe

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Mouth or jaw pain or swelling; loosening of teeth
- Severe pain in your back, hips, thighs, wrists or other bones that may symptoms of broken bones
- Pain, swelling or hardening of a vein in your arm or leg
- Irregular heartbeat, fainting, swelling in your legs or belly
- Pain in your chest, belly or arm
- Sudden loss of vision, speech or the ability to use your arms or legs
- Signs of an allergy such as severe rash, swollen face, lip or tongue, chest or throat tightness
- Lower back pain, body swelling, passing little or no pee, yellow skin, eyes or recent weight gain
- Yellowish skin or eyes, unusually dark pee or pain on the right side of your belly

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses,

denosumab

directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.