

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrEVENTITY™

(pronounced Ē-ven-î-tēē)

romosozumab injection

Single-Use Prefilled Syringe

Read this carefully before you start taking **EVENTITY** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your health care professional about your medical condition and treatment and ask if there is any new information about **EVENTITY**.

Serious Warnings and Precautions

Potential risk of heart attack and stroke and death from heart or blood vessel problems

- **EVENTITY** may increase the risk of a heart attack (myocardial infarction), stroke, and death from heart or blood vessel problems. The risk is increased in patients who had a heart attack or stroke or other types of heart or blood vessel problems. It is not recommended you take **EVENTITY** should you have had a heart attack or stroke. Contact your health care provider if you have any heart or blood vessel problems; discuss the benefits and risks of using **EVENTITY** with them.
- During **EVENTITY** treatment, if you have signs or symptoms of heart attack, such as chest pain or pressure, shortness of breath, light-headedness or dizziness, contact your health care provider or get medical help right away.
- During **EVENTITY** treatment, if you have signs or symptoms of stroke such as headache, numbness or weakness in the face, arms or legs, difficulty talking, or changes in vision or loss of balance, contact your health care provider or get medical help right away.

What is **EVENTITY used for?**

EVENTITY contains romosozumab, a medicine that helps build bone, which makes bone stronger and less likely to break. **EVENTITY** is used to treat osteoporosis in women after menopause who are at high risk of fracture (broken bone).

Osteoporosis is a disease that makes your bones thin and fragile. Osteoporosis is most common in women following menopause. Many patients with osteoporosis have no symptoms, but they are still at risk of breaking bones because osteoporosis has made their bones weak.

How does **EVENTITY work?**

EVENTITY works differently than other osteoporosis medications. **EVENTITY** inhibits a protein called sclerostin. By binding and preventing the activity of sclerostin, **EVENTITY** promotes bone building and also decreases the breakdown of bone. **EVENTITY**'s dual effect of both building new bone and also decreasing breakdown of existing bone will strengthen your bones, improve your bone mass, and lower your chance of breaking bones.

What are the ingredients in EVENITY?

Medicinal ingredients: romosozumab.

Non-medicinal ingredients: acetate, calcium, polysorbate 20, sodium hydroxide, sucrose, and water for injection.

EVENITY comes in the following dosage forms:

- Each 1.17 mL prefilled syringe contains 105 mg of romosozumab (90 mg/mL). Each carton contains two single-use prefilled syringes.

Do not use EVENITY:

- If you have low calcium levels in your blood (hypocalcemia). Your health care provider can tell you if your levels are too low.
- If you are allergic to EVENITY or any of the other ingredients of this medicine (listed in **What are the ingredients in EVENITY?** section).

To help avoid side effects and ensure proper use, talk to your health care professional before you take EVENITY. Talk about any health conditions or problems you may have including, if you:

- Have a history of heart attack, stroke or other heart or blood vessel problems
- Have low calcium levels in your blood (hypocalcemia)
- Have kidney problems or are on dialysis
- Have problems with your teeth or gums and/or have plans for dental work or dental surgery

Other warnings you should know about:

EVENITY may cause low levels of calcium in your blood (hypocalcemia). Your health care provider may prescribe calcium and vitamin D supplements to help prevent low calcium levels in your blood while you take EVENITY. Take calcium and vitamin D as your health care provider tells you to. Contact your health care provider if you notice any of these symptoms:

- Spasms, twitches, or muscle cramps and numbness or tingling in your fingers, toes, or around the mouth.

Serious allergic reactions can happen with use of EVENITY. Call your health care provider or get emergency medical help right away if you have any symptoms of an allergic reaction:

- Rash, hives, and swelling usually of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing.

Serious jaw bone problems (osteonecrosis) can occur during treatment with EVENITY. Your health care provider may tell you to see a dentist before you start EVENITY. Take good care of your teeth and gums while you are taking EVENITY. Contact your health care provider and dentist right away:

- If you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge.

Unusual fractures in the thigh bone can occur during treatment with EVENITY. Contact your doctor if you notice any of these symptoms:

- New or unusual pain in your hip, groin, or thigh

Children and adolescents

The use of EVENITY in children and adolescents has not been studied.

Pregnancy and breast-feeding

EVENITY is not intended for use if you are pregnant. EVENITY has not been tested in pregnant women. It is not known if EVENITY may harm your unborn baby; however EVENITY use in pregnant animals caused harm to their offspring. Tell your health care provider if you are pregnant; think you may be pregnant; or plan to get pregnant.

It is not known if EVENITY is present in breast milk. Tell your health care provider if you are breast-feeding or plan to do so.

Tell your health care provider about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take EVENITY:

EVENITY is administered once every month. EVENITY is injected under your skin (subcutaneous) by a trained individual.

During treatment with EVENITY, you should take calcium and vitamin D as directed by your health care provider.

Ask your health care provider if you have any further questions on the use of EVENITY.

Usual dose:

The usual dose of EVENITY is 210 mg once a month.

EVENITY is administered subcutaneously as 2 injections once every month for one year.

Overdose:

There is no experience with overdosage with EVENITY.

If you think you have taken too much EVENITY, contact your health care professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

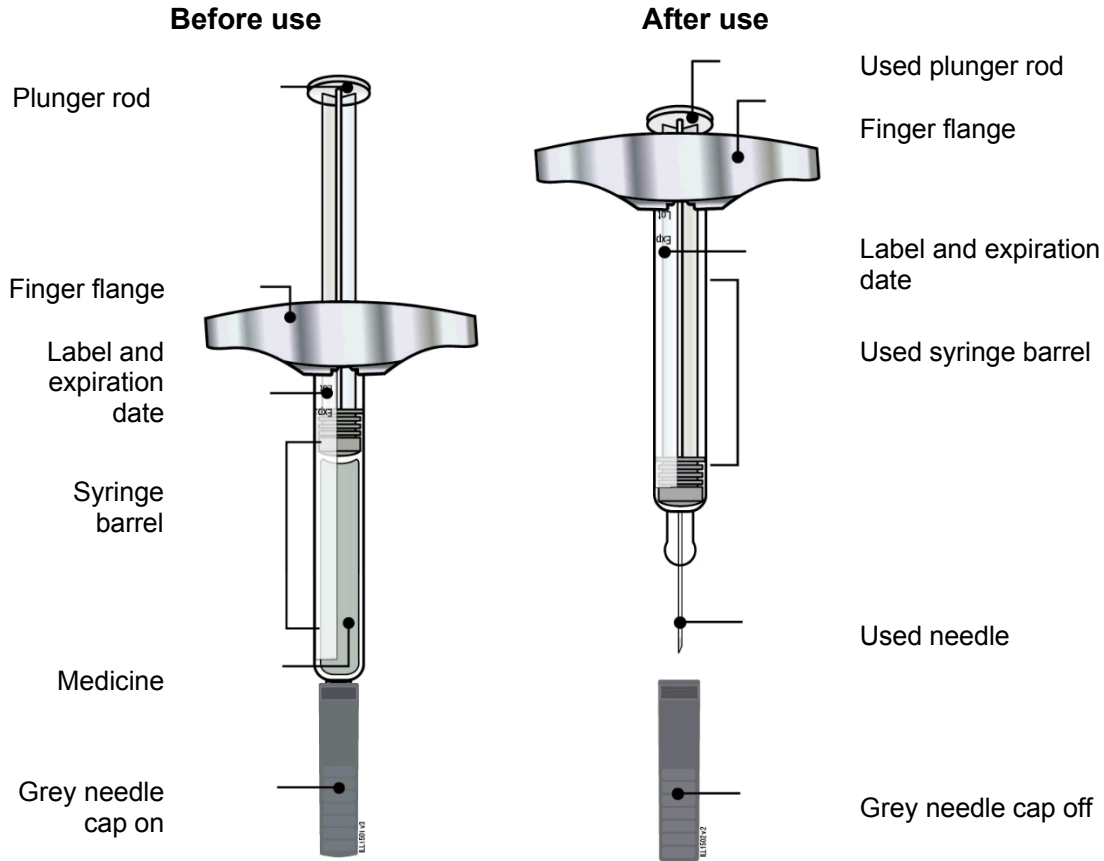
Missed Dose:

If you miss a dose of EVENITY, contact your health care provider as soon as possible to schedule your next dose. After that injections should be scheduled every month from the date of the last injection.

EVENTITY Single-Use Prefilled Syringe:

The following instructions are for preparing and giving an injection of EVENTITY using a single-use prefilled syringe.

Guide to Parts



Important: Needle is inside

Important:

Before you use an EVENTITY prefilled syringe, read this important information:

Use both syringes in this carton for one full dose.

Storing the EVENTITY prefilled syringe

- Keep the syringe out of the reach of children.
- Keep the syringe in the original carton to protect from light or physical damage.
- The syringe should be kept in the refrigerator at 2° C to 8° C.
- If needed, you may store the syringe at room temperature (up to 25° C) in the original carton for up to 30 days. Throw away EVENTITY that has been stored at room temperature after 30 days in appropriate sharps container.

- **Do not** store the syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- **Do not** freeze.

Using the EVENITY prefilled syringe

- Administration should be performed by an individual who has been trained to administer EVENITY.
- **Do not** use a syringe after the expiration date on the label.
- **Do not** shake the syringe.
- **Do not** remove the grey needle cap from the syringe until you are ready to inject.
- **Do not** freeze or use the syringe if it has been frozen.
- **Do not** use a syringe if it has been dropped on a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new syringe.
- The syringe is not made with natural rubber latex.

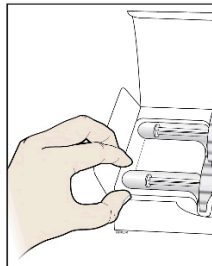
Step 1: Prepare



Read this before you inject.

- To deliver a full dose, inject **two** 105 mg syringes, one after the other.

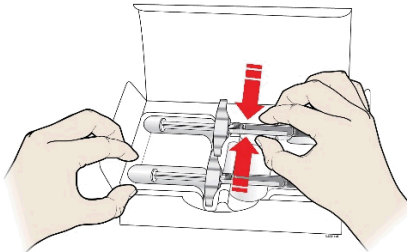
A. Remove two syringes from the carton.



Place finger or thumb on edge of tray to secure it while you remove syringe.

Grab the syringe barrel to remove the syringe from the tray.

Grab Here



For safety reasons:

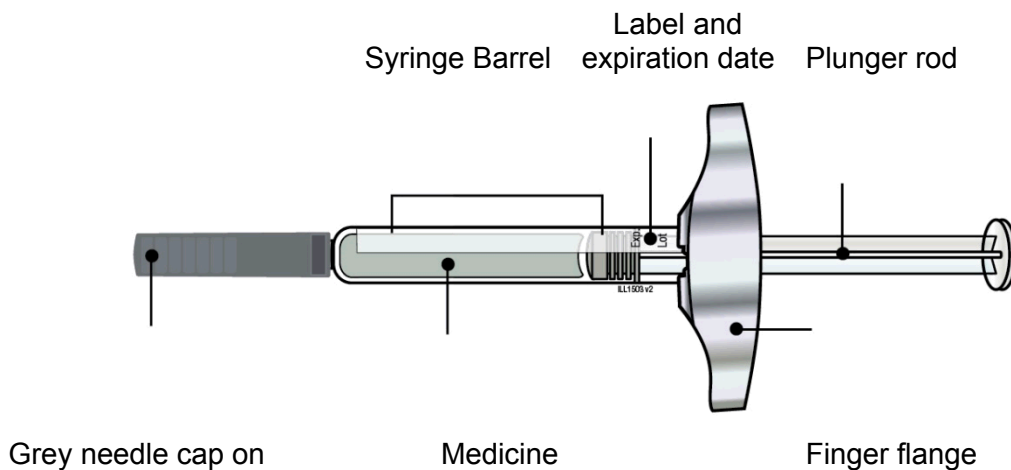
- **Do not** grasp the plunger rod.
- **Do not** grasp the grey needle cap.
- **Do not** remove the grey needle cap until you are ready to inject.
- **Do not** remove the finger flange. This is part of the syringe.

Leave the syringes at room temperature for at least 30 minutes before injecting for patient's comfort.

- **Do not** put the syringes back in the refrigerator once they have reached room temperature.
- **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- **Do not** leave the syringes in direct sunlight.
- **Do not** shake the syringes.

Important: Always hold the prefilled syringe by the syringe barrel.

B. Inspect the syringe.



Always hold the syringe by the syringe barrel.

Make sure the medicine in the syringe is clear and colourless to light yellow.

- **Do not** use the syringe if the medicine is cloudy or discoloured or contains particles.
- **Do not** use the syringe if any part appears cracked or broken.
- **Do not** use the syringe if the grey needle cap is missing or not securely attached.
- **Do not** use the syringe if the expiration date printed on the label has passed.

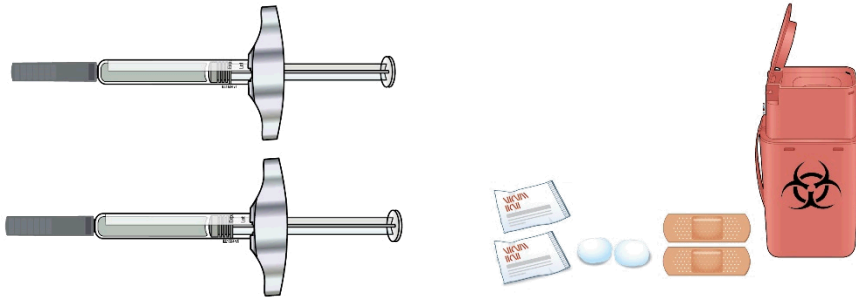
In all cases, use a new syringe and call Amgen Medical Information at 1-866-502-6436.

C. Gather all materials needed for the injection.

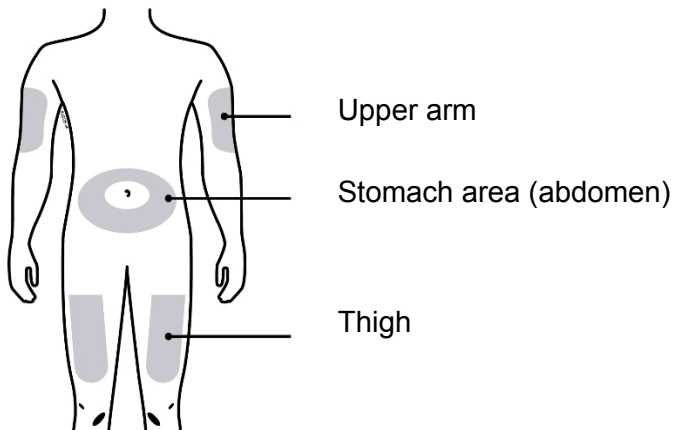
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- Two syringes
- Two alcohol wipes
- Two cotton balls or two gauze pads
- Two adhesive bandages
- Sharps disposal container

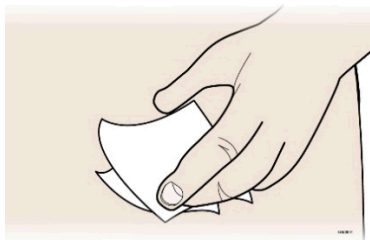


D. Prepare and clean two injection sites, one for each of the two injections.



You can use:

- The thigh
- Stomach area (abdomen), except for a two-inch (five centimeters) area right around the navel
- Outer area of upper arm



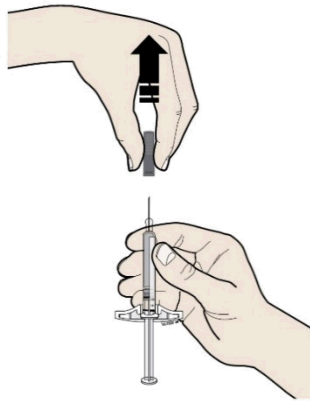
Clean the injection sites with alcohol wipes.

Let the skin dry.

- **Do not** touch this area again before injecting.
- Choose a different site each time you give an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site you used for the previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.
- Avoid injecting directly into raised, thick, red, or scaly skin patch or lesion, or areas with scars or stretch marks.

Step 2: Get ready

- E. Choose the first syringe. Pull the grey needle cap straight off and away from the body when you are ready to inject.

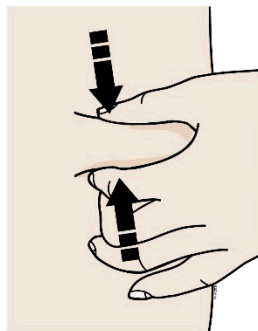


It is normal to see a drop of liquid at the end of the needle.

- **Do not** twist or bend the grey needle cap.
- **Do not** put the grey needle cap back onto the syringe.
- **Do not** remove the grey needle cap from the syringe until you are ready to inject.

Important: Throw the needle cap into a sharps disposal container.

- F. Pinch the injection site to create a firm surface.

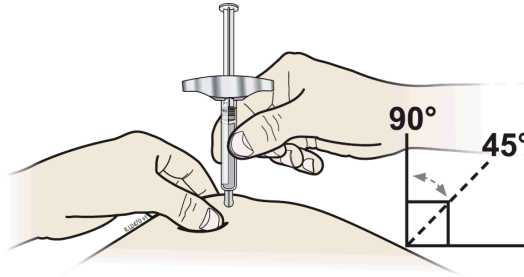


Pinch skin firmly between your thumb and fingers, creating an area about two inches wide (five centimeters).

Important: Keep skin pinched while injecting.

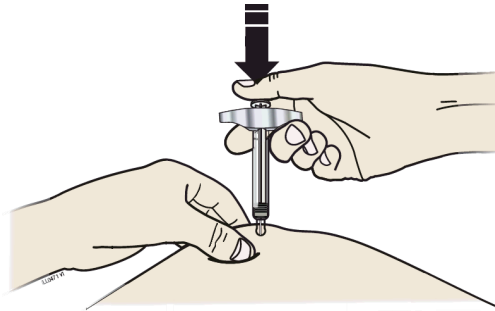
Step 3: Inject

- G. Hold the pinch. With the grey needle cap off, insert the syringe into the skin at 45 to 90 degrees.

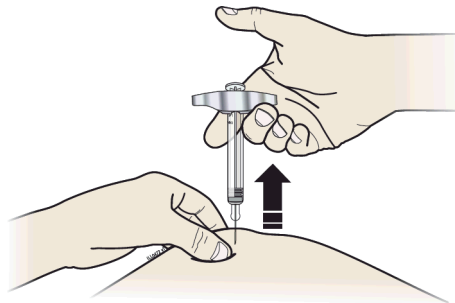


Do not place your finger on the plunger rod while inserting the needle.

- H. Using slow and constant pressure, push the plunger rod all the way down until it stops moving.



- I. When done, release your thumb and gently lift the syringe off of the skin.



Note: After you remove the syringe from skin, the syringe barrel should be empty.

Important: If it looks like the medicine is still in the syringe barrel, this means you have not delivered a full injection.

Step 4: Finish

J. Discard the used syringe and the grey cap.



Put the used syringe in a sharps disposal container right away after use. **Do not** throw away (dispose of) the syringe in your household trash.

If you do not have a sharps disposal container, you may use a container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used needles and syringes.

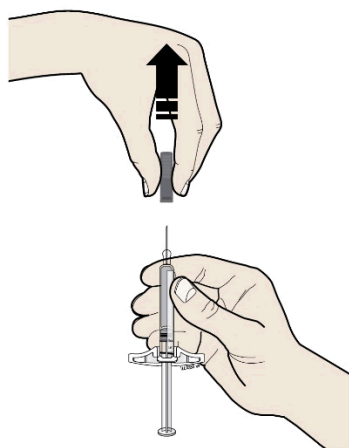
- **Do not** reuse the syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

K. Examine the injection site.

If there is blood, press a cotton ball or gauze pad on the injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

L. Repeat all steps with the second syringe to inject the full dose.



What are possible side effects from using EVENITY?

These are not all the possible side effects you may feel when taking EVENITY. If you experience any side effects including those not listed here, contact your health care professional. Please also see the warnings information above.

Like all medicines, EVENITY can cause side effects, although not everybody gets them.

Possible side effects of EVENITY may include:

- Common cold (viral upper respiratory tract infection)
- Joint pain (arthralgia)
- Back pain
- Pain and redness at the site where EVENITY was injected

Serious side effects and what to do about them			
Symptom / effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON^a (≥ 1%, 1 to 10% of patients) Allergic reaction (hypersensitivity)		√	√
UNCOMMON^a (≥ 0.1%, < 1% of patients) Low levels of calcium in the blood (hypocalcemia)		√	√
Heart attack (myocardial infarction) ^b		√	√
Stroke ^b		√	√

Serious side effects and what to do about them			
Symptom / effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE^a (≥ 0.01%, < 0.1% of patients) Sore in mouth involving gums or jaw bones (osteonecrosis of the jaw) ^b Unusual thigh bone fractures (atypical femoral fracture) ^b		√ √	√ √

^a Frequency regardless of seriousness

^b Positively adjudicated

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your health care professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage

- Refrigerate at 2°C to 8°C in the original carton.
- If removed from the refrigerator, EVENITY should be kept at room temperature (up to 25°C) in the original carton and must be used within 30 days.
- Protect EVENITY from direct light and do not expose to temperatures above 25°C.
- Do not freeze.
- Do not store EVENITY in extreme heat or cold.
- Do not shake.
- Keep EVENITY out of the reach of children.
- Any unused product or waste material should be disposed of in accordance with local requirements.

If you want more information about EVENITY:

- Talk to your health care professional
- Find the full product monograph that is prepared for health care professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.amgen.ca or by calling 1-866-50-AMGEN (1-866-502-6436).

This leaflet was prepared by Amgen Canada Inc.

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