

MEDICATION GUIDE

EVENTITY™ (E-ven-i-tee)

(romosozumab-aqqg)

injection, for subcutaneous use

What is the most important information I should know about EVENTITY?

EVENTITY can cause serious side effects, including:

- **increased risk of having a heart attack, stroke, or death from a cardiovascular (heart or blood vessel) problem.** Call your healthcare provider or get emergency help right away if you have any of the symptoms listed below.
 - Symptoms of **heart attack** may include:
 - chest pain or pressure
 - shortness of breath
 - feeling light-headed or dizzy
 - Symptoms of **stroke** may include:
 - headache
 - numbness or weakness in face, arm, or legs
 - difficulty talking
 - changes in vision or loss of balance

Before you receive EVENTITY, tell your healthcare provider if you have had a heart attack or stroke, especially if it has happened in the past year.

See “**What are the possible side effects of EVENTITY?**” below for other side effects of EVENTITY.

What is EVENTITY?

EVENTITY is a prescription medicine used to:

- treat osteoporosis (thinning and weakening of bone) in women after menopause (“change of life”) who:
 - are at high risk of fracture (broken bone), or
 - cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

It is not known if EVENTITY is safe and effective in children.

Do not receive EVENTITY if you:

- have been told by your healthcare provider that your blood calcium level is too low.
- are allergic to romosozumab or any of the ingredients in EVENTITY. See the end of this Medication Guide for a complete list of ingredients in EVENTITY.

Before receiving EVENTITY, tell your healthcare provider about all your medical conditions, including if you:

- have a history of other heart or blood vessel problems
- have low blood calcium
- cannot take daily calcium and vitamin D
- have kidney problems or are on kidney dialysis
- plan to have dental surgery or teeth removed

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive EVENTITY?

- EVENTITY is an injection that will be given to you by your healthcare provider. EVENTITY is injected under your skin (subcutaneous).
- You will receive an EVENTITY dose (2 injections) 1 time every month for 12 doses.
- You should take calcium and vitamin D while you receive EVENTITY.
- If you miss a dose of EVENTITY, contact your healthcare provider as soon as possible to schedule your next dose. Your next dose of EVENTITY should then be scheduled every month from the date of the last injection.
- You should take good care of your teeth and gums while you receive EVENTITY. You should tell your dentist that you are receiving EVENTITY before you have dental work.

What are the possible side effects of EVENTITY?

EVENTITY may cause serious side effects, including:

See “**What is the most important information I should know about EVENTITY?**”

- **Serious allergic reactions.** Serious allergic reactions have happened in people who receive EVENTITY. Call your healthcare provider or go to the nearest emergency room right away if you have any symptoms of a serious allergic reaction. Symptoms of a serious allergic reaction may include:
 - rash
 - hives
 - swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing
- **Low calcium levels in your blood (hypocalcemia).** EVENTITY may lower the calcium levels in your blood. Your low blood calcium should be treated before you receive EVENTITY. Call your healthcare provider if you have symptoms of low blood calcium such as:
 - spasms, twitches, or cramps in your muscles
 - numbness or tingling in your fingers, toes or around your mouth

- **Severe jaw bone problems (osteonecrosis).** Severe jaw bone problems may happen when you take EVENITY. Your healthcare provider should examine your mouth before you start EVENITY.
 - Your healthcare provider may tell you to see your dentist before you start EVENITY. Ask your healthcare provider or dentist about good mouth care.
- **Unusual thigh bone fractures.** Symptoms of this type of fracture include:
 - new or unusual pain in your hip, groin, or thigh.

The most common side effects of EVENITY include:

- joint pain
- headache

These are not all the possible side effects of EVENITY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EVENITY if I need to pick it up from a pharmacy?

- Keep EVENITY in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect it from light.
- Do not freeze EVENITY.
- Do not shake EVENITY.
- When you remove EVENITY from the refrigerator, EVENITY must be kept at room temperature up to 77°F (25°C) in the original carton and must be used within 30 days. EVENITY should be thrown away if taken out of the refrigerator and not used within 30 days.
- Do not keep EVENITY at temperatures above 77°F (25°C). Warm temperatures will affect how EVENITY works.

Keep EVENITY and all medicines out of the reach of children.

General information about EVENITY

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about EVENITY that is written for health professionals.

What are the ingredients in EVENITY?

Active ingredient: romosozumab-aqqg

Inactive ingredients: acetate, calcium, polysorbate 20, sodium hydroxide, sucrose and water for injection.

Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799

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For more information, go to www.evenity.com or call Amgen at 1-800-772-6436.



This Medication Guide has been approved by the U.S. Food and Drug Administration.

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