

## Package leaflet: Information for the user

### EVENTITY® injection, for subcutaneous use 105 mg/1.17 mL (90 mg/mL) (romosozumab)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What EVENTITY is and what it is used for
2. What you need to know before you use EVENTITY
3. How EVENTITY is given
4. Possible side effects
5. How to store EVENTITY
6. Contents of the pack and other information

#### **1. What EVENTITY is and what it is used for**

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.

#### **2. What you need to know before you use 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 section “**Possible side effects**” below for other side effects of EVENITY.

**Do not use EVENITY 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 EVENITY. See the end of this package leaflet for a complete list of ingredients in EVENITY.

**Before receiving EVENITY, 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.

**Pregnancy and breast-feeding**

EVENITY is only intended to treat women after menopause.

EVENITY should not be used by women of child-bearing potential, or when pregnant or breast-feeding. It is not known whether EVENITY may harm an unborn or breast-fed child.

Contact your doctor if you have any questions.

**Driving and using machines**

EVENITY is expected to have no effect or very little effect on the ability to drive and use machines.

**EVENITY contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say, essentially ‘sodium-free’.

**3. How EVENITY is given**

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

**If you use more EVENITY than you should**

If, by mistake, you have used more EVENITY than you should, contact your doctor or pharmacist.

**If you forget to use or cannot take EVENITY at your usual time**

If you miss a dose of EVENITY, contact your doctor as soon as possible to schedule another dose. Thereafter, the next dose should be given not earlier than one month after the date of the last dose.

**If you stop taking EVENITY**

If you are considering stopping EVENITY treatment, please discuss this with your doctor. Your doctor will advise you on how long you should be treated with EVENITY.

**4. Possible side effects**

**EVENITY may cause serious side effects, including:**

See section “**What you need to know before you use EVENITY**”

- **Serious allergic reactions.** Serious allergic reactions have happened in people who receive EVENITY. 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).** EVENITY may lower the calcium levels in your blood. Your low blood calcium should be treated before you receive EVENITY. 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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store EVENITY**

- Keep EVENITY in a refrigerator at 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 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 25°C. Warm temperatures will affect how EVENITY works.

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

## **6. Contents of the pack and other information**

### **What EVENITY contains**

Each single use prefilled syringe (90 mg/mL) delivers 1.17 mL of solution containing 105 mg of romosozumab, acetate (3.8 mg), calcium (0.61 mg), polysorbate 20 (0.07 mg) and sucrose (70 mg) in Water for Injection and sodium hydroxide to a pH of 5.2.

### **What EVENITY looks like and contents of the pack**

EVENTITY is a clear to opalescent, colourless to light yellow solution for injection provided in a single use disposable pre-filled pen. The syringe inside the pen is made of plastic with a stainless steel needle.

Pack size of 2 pre-filled pens.

Not all pack sizes may be marketed.

#### **General information about EVENTITY**

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

#### **Marketing Authorization Holder and Manufacturer**

##### **Marketing Authorization Holder:**

Amgen Inc.

One Amgen Center Drive

Thousand Oaks, CA 91320-1799, USA

##### **Site of Manufacture of the Drug Product:**

Patheon Italia S.p.A.

Viale Gian Battista Stucchi 110,

Monza, - 20900 Italy

##### **Site of batch release:**

Amgen Manufacturing Limited

State Road 31

Kilometer 24.6

Juncos 00777-4060

Puerto Rico

USA

**This leaflet was last revised in April 2019.**

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder.

This package leaflet has been approved by the U.S. Food and Drug Administration.

To report any side effects:  
Saudi Arabia:

- The National Pharmacovigilance Centre (NPC):
- SFDA Call Center: 19999
- E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)
- Website: <https://ade.sfd.gov.sa/>

#### **THIS MEDICINE**

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,  
Union of Arab Pharmacists.