



# EVENTITY®(romosozumab)

## Patient Alert Card

This card contains important information. Carry it with you during and for one month after EVENTITY treatment. Show it to any doctor or other healthcare professional you see.

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).



Any suspected adverse reactions should be reported immediately in accordance with local spontaneous reporting contacts.

Amgen Local Safety Contacts

Tel: +966 11 2799328

Email: [Safety-MEA@amgen.com](mailto:Safety-MEA@amgen.com)

Or

Saudi Food & Drug Authority (SFDA), National Pharmacovigilance Center (NPC)

Call Center: 19999

Toll free phone: 8002490000

Fax: +966 11 2057662

Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa) Website: <http://ade.sfda.gov.sa/>

Please read the EVENTITY Package Leaflet for further information.

Version 1.0

March 2021

## How to take your treatment

**TWO INJECTIONS** must be given for **EACH MONTHLY DOSE** – one immediately after the other, in the abdomen, thighs or upper arms.

EVENTITY should be administered by a healthcare provider.

Write down the date that each monthly dose of two injections was given.

At the last dose ensure you discuss with your doctor what follow-on therapy to start.

Monthly dose	Date of two injections	Monthly dose	Date of two injections
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

### Contact details

Doctor's name (who prescribed EVENTITY): \_\_\_\_\_

Doctor's telephone: \_\_\_\_\_

My name: \_\_\_\_\_

My telephone: \_\_\_\_\_

Emergency contact name: \_\_\_\_\_

Emergency contact telephone: \_\_\_\_\_

## Important information for PATIENTS AND THEIR CAREGIVERS

EVENTITY helps strengthen bones and helps reduce the risk of breaking bones. Like all medicines, there is a risk of developing side effects. These may include:

### Low levels of calcium in the blood (hypocalcaemia)

**During EVENTITY treatment, tell your doctor if you develop:**

- Spasms, twitches, or cramps in your muscles.
- Numbness or tingling in your fingers, toes or around your mouth.

Take calcium and vitamin D supplements to help prevent low calcium levels as instructed, if these are prescribed by your doctor.

### Problems with your mouth, teeth or jaw

There have been rare reports of osteonecrosis of the jaw (ONJ) in patients who have received EVENTITY. ONJ is a potentially serious condition that can present as a sore in the mouth through which the jaw bone is sometimes visible.

**Contact your doctor immediately if you develop any problems with your mouth or teeth, such as:**

- Loose teeth.
- Pain or swelling.
- Mouth sores that do not heal.
- Pus discharge.

**To reduce the risk of ONJ, during treatment:**

- Maintain good oral hygiene and receive routine dental check-ups.
- Make sure dentures fit properly if you wear them.
- Inform your doctor of any planned dental treatment or dental surgery (e.g. tooth extractions).
- Inform your dentist you are being treated with EVENTITY prior to any dental treatment.

## Increased risk of having a heart attack, stroke or death from a cardiovascular (heart or blood vessel) problem

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

Call your healthcare provider or get emergency help right away if you have any of the symptoms listed below.

- chest pain or pressure
- shortness of breath
- feeling light-headed or dizzy
- headache
- numbness or weakness in face, arm, or legs
- difficulty talking
- changes in vision or loss of balance

## Important information for HEALTHCARE PROFESSIONALS

This patient is being treated with EVENITY (romosozumab).

**HYPOCALCAEMIA** was observed in patients receiving EVENITY.

- Hypocalcaemia is a contraindication.
- Adequately supplement patients with calcium and vitamin D.
- Monitor patients for signs and symptoms of hypocalcaemia, and measure serum calcium levels if hypocalcaemia is suspected.
- In patients with severe renal impairment or receiving dialysis, calcium levels should be monitored.

**OSTEONECROSIS OF THE JAW (ONJ)** has been reported rarely in patients receiving EVENITY.

- Encourage patients to maintain good oral hygiene, receive routine dental check-ups, and promptly report oral symptoms.
- Refer patients suspected of having ONJ to a dentist or an oral surgeon with expertise in ONJ.
- Consider discontinuing Evenity until the condition resolves and contributing risk factors are mitigated where possible.

**MYOCARDIAL INFARCTION (MI) and STROKE** were observed in patients receiving EVENITY.

See full prescribing information for complete boxed warning.

- EVENITY may increase the risk of myocardial infarction, stroke and cardiovascular death.

- EVENITY is contraindication in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors.
- If a patient experiences a myocardial infarction or stroke during therapy, EVENITY should be discontinued.

Consult the EVENITY Summary of Product Characteristics (SmPC) for more information.