



EVENITY®▼ (romosozumab) Patient Alert Card

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



▼ 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. By reporting side effects you can help provide more information on the safety of this medicine.

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Please read the EVENITY package leaflet for further information.

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. Detailed information about how to inject is provided in the Instructions for Use at the back of the package leaflet.

The injections should only be given by a person who has been properly trained.

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 EVENITY):

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.



Heart attack and stroke

Heart attack and stroke have been reported in people receiving EVENTITY.

Do not take EVENTITY if you have had a heart attack or stroke.

Seek immediate medical attention if you get:

- Chest pain.
- Shortness of breath.
- Headache.
- Numbness, or weakness in your face, arms or legs.
- Difficulty talking.
- Changes in vision.
- Loss of balance.

Your doctor will carefully evaluate the risk of cardiovascular problems before he/she lets you start treatment with EVENTITY. Tell your doctor if you know that you have an increased risk of cardiovascular problems such as established cardiovascular disease, high blood pressure, high blood fat levels, diabetes, smoking or kidney problems.

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient is being treated with EVENTITY (romosozumab).

TRANSIENT HYPOCALCAEMIA was observed in patients receiving EVENTITY.

- 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.

MYOCARDIAL INFARCTION (MI) AND STROKE were observed in patients receiving EVENTITY.

- History of MI or stroke is a contraindication.
- Discontinue EVENTITY if a patient experiences a myocardial infarction or stroke during therapy.

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

- 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 EVENTITY until the condition resolves and contributing risk factors are mitigated where possible.



Healthcare professionals can view information on key risks and their management on the website: www.romosozumabrmpeu
Consult the EVENTITY Summary of Product Characteristics (SmPC) for more information.