If you experience any side effects, (this includes any side effects not listed in the Package Leaflet), contact your doctor, pharmacist, or nurse. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie

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

Adverse events should also be reported to UCB (Pharma) Ireland Ltd via UCBCares on 1800 930075 (freephone) or by email UCBCares.IE@ucb.com

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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.



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

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 the rapy to start.

Please read the Evenity package leaflet for further information.

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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

Evenity 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 Evenity 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 Evenity. ONJ is a potentially serious condition that can present as a sore in the mouth through which the jawbone is sometimes visible.

Contact your doctor imminently 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 checkups.
- 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 Evenity prior to any dental treatment.



Heart attack and stroke

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

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

Seek immediate medical attention if you get:

Chest pain

- Difficulty talking
- Shortness of breath
- Changes in vision

Headache

- Loss of balance
- Numbness, or weakness in your face and arms

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

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient is being treated with Evenity (romosozumab).

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

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

TRANSIENT 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.



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