▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

If you get any side effects, talk to your doctor, pharmacist, on (+44) 01753 777100 or 0800 279 3177 (freephone) or by

Approval by United Kingdom authorities: March 2020

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UK-N-RM-OP-1900023 Date of preparation: February 2020



EVENITY®▼ (romosozumab) Patient Alert Card

This card contains important information. Carry it with you during and for one month after **Evenity treatment. Show this card** to any doctor or other healthcare professional that treats you.



MHRA Date of approval: 03.2020

Monthly dose	Administration date of Evenity	Monthly dose	Administration date of Evenity
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

Please record	your treatmen	t details
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C	O	N	TA	C	Т	D	Е	T/	١	LS	

Emergency contact telephone:

CONTACT DETAILS	
Doctor's name (who prescribed Evenity):	
Doctor's telephone:	
My name:	
My telephone:	
Emergency contact name:	
=	

Please read the Evenity package leaflet for further information.

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.

Tell your doctor if you have or have ever had severe kidney problems, kidney failure or have needed dialysis.



Problems with your mouth, teeth or jaw

There have been rare reports of osteonecrosis of the jaw (ONJ; bone damage in the jaw) in patients who have received Evenity. It is important to try to prevent ONJ developing, as it may be a painful condition that can be difficult to treat.

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 Evenity prior to any dental treatment.

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

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



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, arms or legs.

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 blood fat 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: https://www.medicines.org.uk/emc/product/10956/smpc Consult the Evenity Summary of Product Characteristics (SmPC) for more information.