



EVENITY[®]
(romosozumab) injection

EVENITY[®]

(romosozumab 105 mg)

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 card format and content were approved by the Ministry of Health in September 2020

HOW TO TAKE YOUR TREATMENT

TWO INJECTIONS must be given for **EACH**

MONTHLY DOSE—Detailed information about how to inject is provided in the “How should you use the medicine” and “Instructions for Use” sections of the Israel package leaflet.

The first dose of EVENITY should be administered by a healthcare provider only. Starting from the second dose, the injection can be performed by an individual who has been properly trained by a healthcare provider only.

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)

EVENTITY may cause low levels of calcium in the blood.

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



Problems with your mouth, teeth or jaw

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1000 people) in patients receiving Evenity. Osteonecrosis of the jaw can also occur after stopping treatment. It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take.

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.
- Discharge.

Before receiving Evenity, tell your doctor or nurse if you:

- Have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction;
- Do not receive routine dental care or have not had a dental check-up for a long time;

- Are a smoker (as this may increase the risk of dental problems);
- Have previously been treated with a bisphosphonate (used to treat or prevent bone disorders, such as osteoporosis);
- Are taking medicines called corticosteroids (such as prednisolone or dexamethasone);
- Have cancer (and receives treatments such as chemotherapy and inhibitors of new blood vessels' growth [angiogenesis inhibitors]);
- Are taking medicines containing denosumab.

Your doctor may ask you to undergo a dental examination before you start treatment with **Evenity**.

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 (eg, 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 within the preceding year. 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 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).

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.

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

- History of MI or stroke within the preceding year is a contraindication.
- Discontinue EVENITY if a patient experiences a myocardial infarction or stroke during therapy.

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.
- Discontinuation of EVENITY should be considered based on benefit-risk assessment.



Healthcare professionals can consult the EVENITY Israeli Prescribing Information for more details

You can report any side effects, you may get to the Ministry of Health via <https://sideeffects.health.gov.il/>
Or report to local distributor Medison:
pv@Medison.co.il

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**Please read the EVENITY ISRAEL
package leaflet for further information.**

Until the approved Israeli Evenity packs* are available on the market, please refer to the attached Israeli Patient Information Leaflet.

*Foreign packs are allowed to be distributed under the provisions of §29C and contain the foreign leaflet.