

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using EVENITY?

EVENITY contains the active ingredient romosozumab. EVENITY is used to treat osteoporosis in women after menopause, and osteoporosis in men. For more information, see Section [1. Why am I using EVENITY?](#) in the full CMI.

### 2. What should I know before I use EVENITY?

Do not use if you have ever had an allergic reaction to romosozumab or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions or take any other medicines.**

For more information, see Section [2. What should I know before I use EVENITY?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with EVENITY and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use EVENITY?

EVENITY is injected under the skin (subcutaneous). You will receive a dose (of 2 injections) once every month for 12 months, unless your doctor tells you otherwise.

More instructions can be found in Section [4. How do I use EVENITY?](#) in the full CMI.

### 5. What should I know while using EVENITY?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Keep all of your doctor's appointments so that your progress can be checked.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using EVENITY.</li><li>• Practice good dental hygiene and have routine check-ups.</li><li>• Take calcium and vitamin D supplements if your doctor has told you to.</li><li>• Tell your doctor if you become pregnant while taking this medicine.</li><li>• Discuss with your doctor the need to switch to another osteoporosis treatment after the end of your treatment with EVENITY.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or lower the dosage unless your doctor tells you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store EVENITY in the refrigerator (2°C to 8°C). Do not freeze. Do not shake.</li><li>• Keep EVENITY in the original pack to protect your medicine from light.</li></ul>

For more information, see Section [5. What should I know while using EVENITY?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include injection site reactions, headache, cold like symptoms including cough, sore throat and runny nose, joint pain, neck pain, swelling of hands, ankles or feet.

Serious side effects include serious allergic reaction, chest pain or pressure, shortness of breath, light-headedness, dizziness, numbness or weakness, difficulty talking, changes in vision, loss of balance, muscle spasms, twitches or cramps, numbness or tingling in the fingers, toes, or around the mouth, loose teeth, mouth or jaw pain/swelling, non-healing mouth sores.

An increase in serious cardiovascular events (heart attack and stroke) has also been reported in patients treated with EVENITY.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# EVENTITY® (E"-ven"-i"-tee)

Active ingredient(s): *romosozumab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using EVENTITY.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EVENTITY.**

**Where to find information in this leaflet:**

- [1. Why am I using EVENTITY?](#)
- [2. What should I know before I use EVENTITY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EVENTITY?](#)
- [5. What should I know while using EVENTITY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using EVENTITY?

**EVENTITY contains the active ingredient romosozumab.**

EVENTITY helps build bone, which makes bones stronger and less likely to break.

**EVENTITY is used to treat:**

- **Osteoporosis in women after menopause, and**
- **Osteoporosis in men.**

EVENTITY inhibits a protein called sclerostin. EVENTITY binds to and prevents the activity of sclerostin. EVENTITY acts both to build new bone and decrease break down of existing bone to strengthen bones, improve bone mass and structure, and lower the chance of breaking bones.

Bone is a living tissue and is renewed all the time. In women, the ovaries produce the hormone oestrogen which helps keep bones healthy. After menopause, the oestrogen level drops which affects the bone renewal cycle so that more bone is lost than made, resulting in a lower bone mass. This leaves bones thin and fragile and may eventually lead to a condition called osteoporosis.

Osteoporosis becomes more common, occurring in women and men, with increasing age. Many people with osteoporosis have no symptoms but they are still at risk of breaking bones (developing fractures), especially in the spine, hips and wrists.

Osteoporosis is a long-term disease. After you finish the prescribed course of EVENTITY, you will need to continue treatment for osteoporosis with another medicine to keep your bones strong.

### 2. What should I know before I use EVENTITY?

#### Warnings

**Do not use EVENTITY:**

- if you have a history of heart attack or stroke.

- if you have low calcium levels in your blood (hypocalcaemia).

Your doctor can tell you if your calcium levels are too low.

If you have not had a recent test, your doctor may check your blood calcium levels before you start to use EVENTITY.

- if you are allergic to romosozumab, any medicines that are produced using Chinese Hamster Ovary cells, or to any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- if you are a child or adolescent.

The use of EVENTITY in this age group has not been studied.

#### Check with your doctor if you:

- are using other medicines to treat osteoporosis, including medicines such as:
  - denosumab (Prolia®), or
  - bisphosphonates.
- have previously had low levels of:
  - calcium, or
  - vitamin D.
- have any problems with your mouth, jaw bone or teeth.
- know that you have an increased risk of cardiovascular problems such as established cardiovascular disease, high blood pressure, high blood cholesterol levels, diabetes, smoking or kidney problems.
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy

Tell your doctor if you are pregnant, think you may be pregnant, or plan to become pregnant.

EVENTITY has not been tested in pregnant women, and is not intended for use if you are pregnant. It is not known if EVENTITY may harm your unborn baby. Your doctor can discuss with you the risks and benefits involved.

#### Breastfeeding

- Tell your doctor if you are breastfeeding or plan to.

It is not known if the active ingredient in EVENTITY passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EVENITY.**

### 4. How do I use EVENITY?

#### How much will you be given

The usual dose of EVENITY is 210 mg.

- To receive a full dose, you will be given two injections, one after the other, on the same day.
- Each injection contains 105 mg.

#### When to take EVENITY

You will receive an EVENITY dose (of 2 injections) once every month for 12 doses.

#### How it is given

EVENITY is given as an injection under the skin. This is called a subcutaneous injection.

Your doctor may decide that you or your carer can inject EVENITY. Your healthcare professional will show you or your carer how to use EVENITY.

#### Do not use EVENITY unless proper training has been given.

See the detailed "Instructions for Use" leaflet provided with the medicine for instructions about the right way to store, prepare, and give your EVENITY injections.

You may leave EVENITY outside of the refrigerator to reach room temperature (up to 25°C) before the injection. This will make the injection more comfortable. If doing this, store the injection in the carton to protect it from light.

#### How long it is given

Continue taking EVENITY for 12 months, unless your doctor tells you otherwise.

When you have finished the 12 months course of EVENITY, you will need to continue treatment for osteoporosis with another medicine to keep your bones strong and less likely to break. Your doctor will advise you.

#### If you forget to use EVENITY

EVENITY should be used regularly at the same time each month. If you miss your dose at the usual time, it should be taken as soon as possible. Then it should be scheduled every month from the date of the last injection.

#### Do not take a double dose to make up for the dose you missed.

#### If you use too much EVENITY

If you think that you have used too much EVENITY, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using EVENITY?

#### Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking EVENITY.
- Take calcium and vitamin D supplements if your doctor has told you to.
- Practice good dental hygiene and have routine dental check-ups.
- If you wear dentures, make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), remind your doctor that you are being treated with EVENITY.

Remind any doctor, dentist or pharmacist who treats you that you are using EVENITY.

#### Call your doctor straight away if you:

- notice spasms, twitches, or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth. You may have low levels of calcium in your blood.
- experience chest pain or pressure, shortness of breath, light-headedness, headache, numbness, or weakness in face, arm, or legs, difficulty talking, changes in vision, dizziness or loss of balance. These could be signs of serious cardiovascular (heart and blood vessel) problems.

Cardiovascular problems, including heart attack or stroke, have been reported in people using EVENITY.

- experience any problems with your mouth or teeth, such as loose teeth, pain or swelling, or non-healing of sores or discharge. Tell your dentist immediately.

Among people who have used EVENITY, a small number have developed severe jaw bone problems. It is not known whether EVENITY caused these jaw bone problems.

- become pregnant while taking this medicine.

#### Tell your doctor if you:

- experience any new or unusual pain in your hip, groin or thigh.

Among people who have used EVENITY, a small number have developed unusual fractures in their thigh bone. It is not known whether EVENITY caused these unusual fractures.

#### Things you should not do

- Do not take EVENITY to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using this medicine or lower the dose without checking with your doctor first. Discuss with your doctor

the need to switch to another osteoporosis treatment after the end of your treatment with EVENITY.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how EVENITY affects you.**

EVENITY has no known effects on the ability to drive or use machines, but as a general precaution, avoid driving soon after you have an injection.

### Drinking alcohol

There is no information on the effects of using EVENITY with alcohol.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

If you need to store EVENITY before use, keep it:

- in the refrigerator between 2°C and 8°C. Do not freeze and do not store above 25°C.
- in the carton protected from light. If you remove the medicine from the carton it may not keep well.

You may leave EVENITY in the original carton outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable.

**Once EVENITY has been left to reach room temperature, it must be used within 30 days or discarded.**

Do not shake.

Do not store EVENITY in extreme heat or cold.

- **Keep EVENITY where young children cannot reach it.**

### When to discard your medicine

After injecting EVENITY, immediately throw away the used syringe into a special sharps container.

Discard any EVENITY that has been removed from the refrigerator for more than 30 days.

### Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or if it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Injection site reaction: redness, bruising or pain around where the injection was given</li> <li>• Cold like symptoms: runny nose, sore throat, cough</li> <li>• Headache</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Joint pain</li> <li>• Neck pain</li> <li>• Swelling of hands, ankles or feet</li> </ul>	<p><b>effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Serious allergic reactions:</b></p> <ul style="list-style-type: none"> <li>• Rash, itching, or hives on the skin</li> <li>• Swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing</li> </ul> <p><b>Symptoms of heart attack:</b></p> <ul style="list-style-type: none"> <li>• Chest pain or pressure in the chest</li> <li>• Shortness of breath</li> <li>• Light-headedness or dizziness.</li> </ul> <p><b>Symptoms of stroke:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Numbness or weakness in face, arm, or legs</li> <li>• Difficulty talking</li> <li>• Changes in vision</li> <li>• Loss of balance</li> </ul> <p><b>Symptoms of low levels of calcium in your blood (hypocalcaemia):</b></p> <ul style="list-style-type: none"> <li>• Muscle spasms, twitches, or cramps</li> <li>• Numbness or tingling in the fingers, toes, or around the mouth</li> </ul> <p><b>Jaw bone problems:</b></p> <ul style="list-style-type: none"> <li>• Loose teeth</li> <li>• Mouth or jaw pain or swelling,</li> <li>• Non-healing of mouth sores or mouth discharge</li> </ul>	<p><b>Call your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What EVENITY contains

<b>Active ingredient (main ingredient)</b>	romosozumab
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• calcium</li><li>• acetate</li><li>• polysorbate 20 (E432)</li><li>• sucrose</li><li>• sodium hydroxide (E524)</li><li>• water for injections</li></ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

**What EVENITY looks like**

EVENITY is a clear to opalescent, colourless to light yellow liquid.

EVENITY is available as a pack that contains two single-use prefilled syringes.

Each 1.17 mL prefilled syringe contains 105 mg romosozumab (90 mg/mL) (AUST R 296831).

The registered pack of two single-use prefilled autoinjector/pens (AUST R 296830) is not currently available in Australia.

**Who distributes EVENITY**

Amgen Australia Pty Ltd,  
Level 11, 10 Carrington Street,  
Sydney NSW 2000.

Ph: 1800 803 638

[www.amgenmedinfo.com.au](http://www.amgenmedinfo.com.au)

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