Evenity® Solution for Injection in Pre-filled Syringe 105mg/1.17ml

Romosozumab (105 mg/1.17 ml)

What is in this Leaflet?

1. What EVENITY is Used for
2. How EVENITY Works
3. Before You Use EVENITY
4. How to Use EVENITY
5. While You are Using EVENITY
6. Side Effects
7. Storage and Disposal of EVENITY
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP Revision

What is the most important information I should know about EVENITY?

EVENITY can cause serious side effects, including:

- increased risk of having a heart attack, stroke, or death from a cardiovascular (heart or blood vessel) problem.

Before you receive EVENITY, tell your doctor if you have had a heart attack or stroke, especially if it has happened in the past year.

See "**While You are Using EVENITY**"

What EVENITY is Used for

EVENITY is used to treat:

- severe osteoporosis in women after menopause, at high risk of fracture

Osteoporosis is a disease that makes your bones thin and fragile. Osteoporosis is most common in women following menopause. Many patients with osteoporosis have no symptoms, but they are still at risk of breaking a bone because osteoporosis has made their bones weak.

How EVENITY Works

EVENITY contains romosozumab, a medicine that helps build bone, which makes bone stronger and less likely to break.

EVENITY inhibits a protein called sclerostin. By binding and preventing the activity of sclerostin, EVENITY rapidly promotes bone building and also decreases break down of bone.

EVENITY's dual effect of both building new bone and also decreasing break down of existing bone will strengthen your bones, improve your bone mass and structure, and lower your chance of breaking bones.

Before You Use EVENITY

Tell your doctor if you had a heart attack or stroke, especially if it happened in the past year.

- *When you must not use it*

Do not use if you have low calcium levels in your blood. Your doctor can tell you if your levels are too low.

Do not use if you are allergic to EVENITY or any of the other ingredients of this medicine.

- *Before you start to use it*

Before you start using EVENITY, tell your doctor about all your medical conditions, including allergies, and if you:

- Have previous history or condition related to low blood calcium levels or serious allergic reactions or heart attack or stroke or jaw bone problem or unusual fractures.
- are pregnant or plan to become pregnant. It is not known if EVENITY will harm your unborn baby. Tell your doctor if you become pregnant while taking EVENITY.
- are breastfeeding or plan to breastfeed. You and your doctor should decide if you will take EVENITY or breastfeed. You should not do both without talking to your doctor first.

- *Taking other medicines*

Tell your doctor or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

How to Use EVENITY

- *How much to use*

EVENITY is administered under the skin (subcutaneously), once every month, up to 12 months. **Inject two 105 mg syringes, one after the other (Total 210 mg).**

- During treatment with EVENITY, you should take calcium and vitamin D as directed by your doctor.
- If your doctor decides that you or a caregiver can administer EVENITY, you or your caregiver should receive training on the right way to prepare and administer EVENITY.

Do not try to administer EVENITY until you have been shown the right way by your doctor or nurse.

Do not administer EVENITY together with other injectable medicines at the same injection site.

- *When to use it*

Use EVENITY exactly as your doctor tells you to use it.

- *How long to use it*

Administer EVENITY once every month, for up to 12 months. After completing the therapy, speak to your doctor about transition to another osteoporosis therapy.

- *If you forget to use it*

If you forget to use EVENITY, contact your doctor as soon as possible to schedule your next dose. After that, injections should be scheduled every month from the date of the last injection.

- *If you use too much (overdose)*

If you use more EVENITY than you should, talk to your doctor or pharmacist.

While You are Using EVENITY

- *Things you must do*

Tell your doctor if you:

- Notice symptoms of low blood calcium like spasms, twitches, or muscle cramps and numbness or tingling in fingers, toes or around the mouth. EVENITY may cause low

levels of calcium in blood. Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take EVENITY. Take calcium and vitamin D as your doctor tells you to.

- Notice symptoms of allergic reaction like rash, hives and swelling of the face, lips, mouth, tongue, or throat which may cause difficulty swallowing or breathing. Serious allergic reactions can happen with use of EVENITY.
- Heart attacks occurred during treatment with EVENITY in clinical studies. It is not known whether EVENITY caused these heart attacks. Call your doctor or get emergency medical help right away if you have symptoms of heart attack, such as chest pain or pressure, shortness of breath, or light-headedness or dizziness.
- Strokes occurred during treatment with EVENITY in clinical studies. It is not known whether EVENITY caused these strokes. Call your doctor or get emergency medical help right away if you have symptoms of stroke, such as headache, numbness or weakness in face, arm, or legs, difficulty talking, changes in vision, or loss of balance.
- Severe jaw bone problems occurred during treatment with EVENITY in clinical studies. It is not known whether EVENITY caused these jaw bone problems. Your healthcare provider may tell you to see your dentist before you start EVENITY. Ask your healthcare provider or dentist about good oral hygiene care. Contact your healthcare provider and dentist right away if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of jaw bone problems.
- Unusual fractures in the thigh bone occurred during treatment with EVENITY in clinical study. It is not known whether EVENITY caused these unusual fractures. Symptoms of this type of fracture include new or unusual pain in your hip, groin, or thigh. Tell your doctor if you notice any of these symptoms.

- *Things you must not do*

Do not use EVENITY for a condition for which it was not prescribed. **Do not** give EVENITY to other people, even if they have the same symptoms that you have. It may harm them.

- *Things to be careful of*

Always check the label of your single-use pre-filled syringe to make sure you have the correct medicine and the correct dose of EVENITY before each administration.

Side Effects

Possible side effects of EVENITY may include:

- Low levels of calcium in the blood
- Allergic reaction
- Redness or pain around the site where the injection was given (injection site reactions)
- Common viral cold (viral upper respiratory tract infection)
- Joint pain
- Headache
- Muscle spasms
- Cough
- Swelling of hands, ankles or feet
- Neck pain

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EVENITY. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of EVENITY

- *Storage*

- Keep the EVENITY pre-filled syringe in the original carton and in the refrigerator between 2°C to 8°C.
- If removed from the refrigerator, the EVENITY pre-filled syringe should be kept at room temperature (up to 25°C) in the original carton and must be used within **30** days.
- Protect the EVENITY pre-filled syringe from direct light and do not expose to temperature above 25°C.
- **Do not** freeze the EVENITY pre-filled syringe or use a EVENITY pre-filled syringe that has been frozen.
- **Do not** shake.

Keep the EVENITY pre-filled syringe out of the sight and reach of children.

- *Disposal*

Put the used syringe in a sharps disposal container right away after use. **Do not** throw away (dispose of) the syringe in your household trash.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

EVENITY is a clear to opalescent, colourless to light yellow liquid. Each pack contains 2 single-use pre-filled syringes. **Do not** use if the solution is cloudy or discoloured or contains particles.

- *Ingredients*

- Active Ingredient: romosozumab
- Inactive Ingredients: calcium, acetate, sucrose, polysorbate 20, water for injection, sodium hydroxide

- *MAL numbers:*

EVENITY Solution for Injection in Pre-filled Syringe 105 mg/1.17 ml
MAL21076004AZ

Manufactured by
Patheon Italia S.p.A.,
Viale G.B. Stucchi 110-20900,
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Released by
Amgen Manufacturing Limited LLC,
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