EMA/571266/2019
EMEA/H/C/004465

Evenity (*romosozumab*)

An overview of Evenity and why it is authorised in the EU

What is Evenity and what is it used for?

Evenity is a medicine used to treat osteoporosis, a disease that makes bones fragile. It is for use in women who have been through the menopause and who have severe osteoporosis (low bone density and previous fracture), leading to a high risk of further fractures.

How is Evenity used?

Evenity can only be obtained with a prescription and treatment should be started and supervised by a specialist doctor with experience in treating osteoporosis. It is available as a prefilled syringe or pen containing 105 mg, to be injected under the skin of the belly, thigh or upper arm; the recommended dose is two injections at different body sites (210 mg in total) given once a month for 12 months.

For more information about using Evenity, see the package leaflet or contact your doctor or pharmacist.

How does Evenity work?

The active substance in Evenity, romosozumab, is a monoclonal antibody (a type of protein) that attaches to a specific target in the body called sclerostin. Sclerostin is a natural substance that plays an important role in regulating the formation and breakdown of bone. By attaching to sclerostin and blocking its action, romosozumab increases the formation of new bone tissue, and reduces the breakdown of existing bone. This helps strengthen bones and reduce the risk of fractures.

What benefits of Evenity have been shown in studies?

Evenity has been studied in two main studies in postmenopausal women with osteoporosis and shown to reduce the incidence of fractures. One study, involving 7,180 women, compared Evenity with a placebo (dummy treatment) while the other, involving 4,093 women with severe osteoporosis, compared the medicine with alendronate, a standard medicine for treating osteoporosis.

In the first study, treatment with Evenity for 12 months reduced the number of new fractures detected by X-ray in the spine compared with placebo (16 cases in 3,321 Evenity-treated women versus 59

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

among 3,322 women given placebo). Benefit continued to be seen at 24 months, during which the women were maintained with another osteoporosis treatment, denosumab.

In the second study, in which 12 months' treatment with Evenity (followed by maintenance treatment with alendronate) were compared with continuous alendronate treatment, Evenity again reduced the number of new fractures detected by X-ray in the spine at 12 months and benefit continued over the 12 months of alendronate maintenance: there were 74 new fractures in the spine detected by X-ray among 1,825 Evenity-treated women over the whole 24 months, compared with 147 among 1,834 women just given alendronate. When all clinical fractures both in the spine and elsewhere were analysed over the course of the study, after about 33 months, the results were 198 fractures among 2,046 given Evenity and 266 among 2,047 in the alendronate group.

What are the risks associated with Evenity?

The most common side effects with Evenity (which may affect more than 1 in 10 people) are nasopharyngitis (inflammation of the nose and throat) and arthralgia (joint pain). Other side effects include allergic reactions and hypocalcaemia (low levels of calcium in the blood).

Serious problems with the heart and circulation such as myocardial infarction (heart attack) and stroke have occurred in some patients treated with Evenity, so the medicine must not be given to patients who have already had a heart attack or a stroke. It must also not be used in patients with hypocalcaemia.

For the full list of side effects and restrictions with Evenity, see the package leaflet.

Why is Evenity authorised in the EU?

The European Medicines Agency decided that Evenity's benefits are greater than its risks in severe osteoporosis and it can be authorised for use in the EU. It took note of the apparent benefits of the medicine in reducing fractures in women with severe osteoporosis, a condition that has a major impact on the quality of patients' lives. Although the Agency was concerned by the possible increase in risk of events such as heart attack and stroke, measures such as ensuring treatment was started and supervised by specialists and avoiding use in women who had already had a heart attack or stroke (and thus were more likely to be affected) offered ways to manage this risk.

What measures are being taken to ensure the safe and effective use of Evenity?

The company that markets Evenity will provide educational materials for doctors and an alert card for patients, providing information on how to use the medicine safely and how to identify and report side effects.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Evenity have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Evenity are continuously monitored. Side effects reported with Evenity are carefully evaluated and any necessary action taken to protect patients.

Other information about Evenity

Evenity received a marketing authorisation valid throughout the EU on 9 December 2019.

Further information on Evenity can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/evenity.

This overview was last updated in 12-2019.