

▼ **EVENITY®**

ROMOSUZUMAB FOR OSTEOPOROSIS

Heart attacks in exchange for fractures. Does it worth?



The risks do not compensate its modest benefit.

REPORT
[IN SPANISH]



IMPORTANT THERAPEUTIC INNOVATION



MODEST THERAPEUTIC INNOVATION



SOME ADDED VALUE IN SPECIFIC SITUATIONS



NO THERAPEUTIC INNOVATION



INSUFFICIENT EVIDENCE



PRODUCT INFORMATION

WHAT IS IT?

Monoclonal antibody with effect on bone remodeling.

INDICATION

Treatment of severe osteoporosis in postmenopausal women at high risk of fracture. In Spain it is financed in women with severe osteoporosis, defined as bone mineral density (≤ -3.0) and high risk of fracture, previously treated with bisphosphonates or with contraindication to those, with a previous fragility fracture, with no history of myocardial infarction, stroke or coronary artery disease. Patients must have a low or moderate cardiovascular risk (REGICOR $< 10\%$, SCORE $< 5\%$).

POSOLGY AND METHOD OF ADMINISTRATION

210 mg (administered as two subcutaneous injections of 105 mg each) once monthly for 12 months.

SPECIAL POPULATIONS

Serum calcium should be monitored in patients with severe renal impairment or receiving dialysis. It is contraindicated in patients with hypocalcaemia or a history of myocardial infarction or stroke.

EFFECTIVENESS

Compared with alendronate 70 mg weekly for 12 months and subsequent open-label extension for another 12 months with weekly alendronate in both arms, it showed superiority at 12 and 24 months in reducing vertebral and clinical fractures. This was not the case in non-vertebral and hip fractures, which are the most clinically relevant for measuring the efficacy of osteoporosis treatments. However, statistical significance was observed in this type of fracture at 33 months in the primary analysis, although 82 patients (95% CI 45 to 500) would have to be treated with romosozumab to avoid a hip fracture.

RISKS

The most common adverse reactions were nasopharyngitis and arthralgia. An increase in serious cardiovascular events (myocardial infarction and stroke) and higher mortality associated with the use of romosozumab was detected. Even excluding the population with a history of myocardial infarction or stroke, two extra major cardiovascular events per 1000 patients would be expected. Osteonecrosis of the jaw, atypical femoral fractures, and hypocalcaemia were also observed.

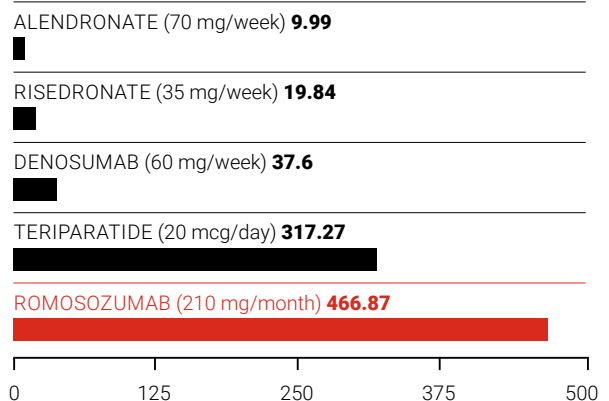
PLACE IN THERAPEUTICS

It is hard to find a profile of patients candidates to romosozumab because of the doubtful clinical relevance of the effects observed in fracture reduction and the safety concerns.

PRESENTATIONS

Evenity® 105 mg solution for injection in pre-filled pen (466.87€)

Cost of treatment/month (€)



OPEN ACCESS

