

EVENITY™ Fact Sheet



EVENITY™ (romosozumab-aqqg) is the **first and only** bone-building agent that simultaneously increases bone formation and, to a lesser degree, decreases bone resorption (or bone-loss) to reduce the risk of fracture,¹ and is approved in the U.S. EVENITY™ is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.^{2,3}

HOW IT WORKS

EVENITY™ is a humanized monoclonal antibody that is designed to work by binding and inhibiting the protein **sclerostin**, a protein naturally occurring in the bone. Sclerostin is responsible for telling our bodies to stop bone formation. By inhibiting sclerostin, studies have shown bone formation **increases** and bone resorption **decreases**.⁴

DATA

The EVENITY™ development program includes 19 clinical studies that enrolled approximately 14,000 patients. EVENITY™ has been studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program included two large fracture trials comparing EVENITY™ to either placebo or active comparator in nearly 12,000 postmenopausal women with osteoporosis. Amgen and UCB co-developed EVENITY™.



EVENITY™ is approved in the U.S. based on the results of two Phase 3 studies:

- In the placebo-controlled FRAME study of **7,180** postmenopausal women with osteoporosis, treatment with EVENITY™ resulted in a significant reduction of new vertebral (spine) fracture at 12 months compared to placebo.⁵
- In the active-controlled ARCH study of **4,093** postmenopausal women with osteoporosis and with prior history of fracture, treatment with EVENITY™ for 12 months followed by 12 months of alendronate significantly reduced the incidence of new vertebral fracture at 24 months.⁶



EVENITY™ is a once-a-month dose (2 injections – 105 mg/1.17 mL) administered by a physician.¹ Following 12 doses of treatment with EVENITY™, patients transition to an antiresorptive follow-up osteoporosis treatment.¹

ABOUT POSTMENOPAUSAL OSTEOPOROSIS

Osteoporosis is a disease characterized by weak bones and is caused by excessive bone loss.⁷ Postmenopausal osteoporosis is the most common form of the disease.⁸ When bones become weak and fragile, even a bump or fall from standing height can lead to a broken bone.⁹ A fracture can have significant consequences, including making it more difficult to get around and to do daily tasks.¹⁰



Worldwide, **8.9 million fractures** due to osteoporosis occur each year – that's a fracture every 3 seconds.¹¹



In the U.S., **1 in 2 women** will experience a fracture due to osteoporosis in their remaining lifetime.¹²



Often there are **no symptoms of osteoporosis** until the first fracture occurs.¹³



People who experience a fragility fracture are **5X more likely to suffer a subsequent, or secondary, fracture within the next 1 to 2 years.**¹⁴





Indication:

EVENITY™ is a prescription medicine used to treat osteoporosis in women after menopause who are at high risk of fracture, or cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

Important Safety Information

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. Call your healthcare provider or get emergency help right away if you have any of these symptoms: symptoms of **heart attack**, which may include: chest pain or pressure; shortness of breath; feeling light-headed or dizzy; or symptoms of **stroke**, which may include: headache; numbness or weakness in face, arm, or legs; difficulty talking; changes in vision or loss of balance. Before you receive EVENITY™, tell your healthcare provider if you have had a heart attack or stroke, especially if it has happened in the past year.

Do not receive EVENITY™ if you: have low blood calcium; or are allergic to romosozumab or any of the ingredients in EVENITY™.

Before receiving EVENITY™, tell your healthcare provider about all your medical conditions, including if you:

- have a history of other heart or blood vessel problems
- have low blood calcium
- cannot take daily calcium and vitamin D
- have kidney problems or are on kidney dialysis
- plan to have dental surgery or teeth removed

What are the possible side effects of EVENITY™?

EVENITY™ may cause serious side effects, including:

Serious allergic reactions have happened in people who receive EVENITY™. Call your healthcare provider or go to the nearest emergency room right away if you have any symptoms of a serious allergic reaction including: rash; hives; swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing.

Low calcium levels in your blood (hypocalcemia). EVENITY™ may lower the calcium levels in your blood. Your low blood calcium should be treated before you receive EVENITY™. Call your healthcare provider if you have symptoms of low blood calcium such as: spasms, twitches, or cramps in your muscles; numbness or tingling in your fingers, toes or around your mouth.

Severe jaw bone problems (osteonecrosis) may occur. Your healthcare provider should examine your mouth before you start EVENITY™ and may tell you to see your dentist. Ask your healthcare provider or dentist about good mouth care.

Unusual thigh bone fractures. Symptoms of this type of fracture include new or unusual pain in your hip, groin, or thigh.

The most common side effects of EVENITY™ include joint pain and headaches.

These are not all the possible side effects of EVENITY™. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying EVENITY™ full Prescribing Information, including Medication Guide.

REFERENCES

- 1 EVENITY™ (romosozumab-aqqg) U.S. Prescribing Information [INSERT LINK]
- 2 [Insert letter from FDA]
- 3 Pharmaceuticals and Medical Devices Agency Prescription Drug Database http://www.info.pmda.go.jp/go/pack/39994C7G1022_1_02/
- 4 Lewiecki. *Ther Adv Musculoskel Dis*. 2014.
- 5 NIH Clinical Trials. Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis (FRAME). <https://clinicaltrials.gov>. Accessed April 8, 2019.
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- 10 International Osteoporosis Foundation. The Global Burden of Osteoporosis: A factsheet. Available at: <https://iofbonehealth.org/sites/default/files/media/PDFs/Fact%20Sheets/2014-factsheet-osteoporosis-A4.pdf>. Accessed April 8, 2019.
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