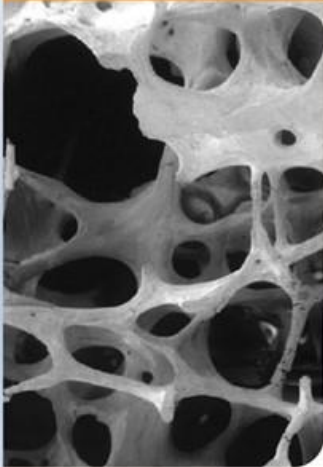


For the treatment of postmenopausal women with osteoporosis at high risk for fracture

YOU ARE CORDIALLY INVITED TO ATTEND AN AMGEN SPEAKER PROGRAM.



© David W. Dempster, PhD, 2000.

12 MONTHS TO STRONGER BONES FOR YOUR PATIENTS

WITH POSTMENOPAUSAL OSTEOPOROSIS AT HIGH RISK FOR FRACTURE¹

Please join us for an educational presentation on the importance of identifying patients with postmenopausal osteoporosis at high risk for fracture, determining their degree of risk, and criteria for the use of anabolic therapy as an appropriate initial therapy option.² With a unique dual effect that both builds bone and to a lesser extent slows bone loss, EVENITY[®] has been shown to build bone rapidly in 12 months and reduce the risk of new vertebral fractures.¹

SPEAKER:

CHAD DEAL, MD

Head, Center for Osteoporosis and Metabolic Bone Disease
Vice Chair Quality and Outcomes Department of Rheumatology

Wednesday, February 26, 2025

6:30 PM Eastern

Lock Keepers Restaurant

Sommelier Room
8001 Rockside Road
Valley View, OH 44125

PLEASE RSVP TO:

Kristy Cingel

Kristi Apelt

PHONE:

(440) 589-8304

(216) 210-8364

E-MAIL:

kcingel@amgen.com

kapelt@amgen.com

INDICATION FOR EVENITY[®]

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.

The anabolic effect of EVENITY[®] wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY[®] use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

IMPORTANT SAFETY INFORMATION

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENITY[®] may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY[®] should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY[®] should be discontinued.

Please see complete Important Safety Information on next page.

IMPORTANT SAFETY INFORMATION

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENITY[®] may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY[®] should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY[®] should be discontinued.

In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with EVENITY[®] compared to those treated with alendronate.

Contraindications: EVENITY[®] is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY[®]. EVENITY[®] is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in EVENITY[®]-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENITY[®].

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENITY[®]. Correct hypocalcemia prior to initiating EVENITY[®]. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on EVENITY[®].

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving EVENITY[®]. A routine oral exam should be performed by the prescriber prior to initiation of EVENITY[®]. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of EVENITY[®] should be considered based on benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving EVENITY[®]. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENITY[®] treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of EVENITY[®] therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions ($\geq 5\%$) reported with EVENITY[®] were arthralgia and headache. EVENITY[®] is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

INDICATION

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. The anabolic effect of EVENITY[®] wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY[®] use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

Please see EVENITY[®] full Prescribing Information, including Medication Guide.

AMGEN