PRODUCT ORDERING SHEET FOR EVENITY®

EVENITY®
(romosozumab-aqqg)
injection 105 mg/1.17 mL

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.

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 additional Important Safety Information on reverse side.

PRODUCT INFORMATION [1]

2 syringes = 1 dose

Description	EVENITY® injection is a clear to opalescent, colorless to light yellow solution for subcutaneous injection supplied in a single-use prefilled syringe. The prefilled syringe is not made with natural rubber latex. Each single-use prefilled syringe contains 105 mg of EVENITY® in a deliverable volume of 1.17 mL.
Quantity	Each EVENITY® carton contains one full dose. To deliver a full dose, the 2 syringes in each carton must be administered.
NDC Number	Select the appropriate NDC from the following as seen on the product carton: 55513-998-02 55513-880-02

PRODUCT ORDER INFORMATION

For product price and ordering information, please contact one of the following wholesalers:

For Clinics	Phone	Website
AndaMEDS Physician and Specialty Distribution (not approved for Oncology/Urology)	855-772-2879	www.andameds.com
Besse Medical	800-543-2111	www.besse.com
Cardinal Health Specialty Solutions	877-453-3972	www.cardinalhealth.com
CuraScript Specialty Distribution (Priority Healthcare Distribution)	877-599-7748	www.curascriptsd.com
Henry Schein, Inc.	800-772-4346	www.henryschein.com
McKesson Medical-Surgical (not approved for Oncology/Urology)	866-625-2679	mms.mckesson.com
McKesson Specialty Health	855-477-9800	www.mckessonspecialtyhealth.com
Metro Medical Supply, Inc.	800-768-2002	www.metromedical.com
Oncology Supply	800-633-7555	www.oncologysupply.com
Cardinal Health PR 120, Inc.*	787-625-4100	www.cardinalhealth.pr
Cesar Castillo, Inc.*	787-999-1616	www.cesarcastillo.net
For Hospitals/Institutions		
AndaMEDS Physician and Specialty Distribution (not approved for Oncology/Urology)	855-772-2878	www.andameds.com
ASD Healthcare	800-837-5403	www.asdhealthcare.com
Cardinal Health Specialty Solutions	855-855-0708	www.cardinalhealth.com
McKesson Plasma & Biologics	877-625-2566	www.mckesson.com
M&D Specialty Distribution, LLC (Div. of Morris & Dickson, LLC)	800-710-6100	www.mdspecialtydist.com
Cardinal Health PR 120, Inc.*	787-625-4100	www.cardinalhealth.pr
Cesar Castillo, Inc.*	787-999-1616	www.cesarcastillo.net

*EVENITY® Authorized Distributors in Puerto Rico.

Important Dosage and Administration Instructions[1]

Two separate syringes (and two separate subcutaneous injections) are needed to administer the total dose of 210 mg of EVENITY®. Inject two 105 mg/1.17 mL prefilled syringes, one after the other. EVENITY® should be administered by a healthcare provider. Since the effects of EVENITY® are reversible with discontinuation of treatment, continued therapy with an antiresorptive agent should be considered.

Dosing and Administration[1]

The recommended dose of EVENITY® is 210 mg administered subcutaneously in the abdomen, thigh, or upper arm. Administer EVENITY® once every month for 12 doses. Patients should be adequately supplemented with calcium and vitamin D during treatment with EVENITY®. If an EVENITY® dose is missed, administer as soon as it can be rescheduled. Thereafter, EVENITY® can be scheduled every month from the date of the last dose.

Storage and Handling Requirements[1]

Refrigerate EVENITY® at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Do not shake. If removed from the refrigerator, EVENITY® can be kept at room temperature (up to 25°C [77°F]) in the original carton and must be used within 30 days. If not used within 30 days, discard EVENITY®.

Do not expose EVENITY® to temperatures above 25°C (77°F).

Product Expiration

The expiration date is printed on each carton and syringe label.

Ordering Information

EVENITY® is available through a network of preferred distributors; visit http://www.amgen.com/partners/wholesalers for more information.

Product Returns

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Returned Goods Policy.

Reimbursement Information

Amgen SupportPlus: 1-866-264-2778
MyAmgenPortal.com.

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1-800-28-AMGEN (1-800-282-6436)
Fax: 1-800-29-AMGEN (1-800-292-6436)
www.amgen.com www.EVENITYProliaHCP.com

For EVENITY® product information, call **Medical Information** at **1-800-77-AMGEN** (1-800-772-6436).

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 (≥ 5%) reported with EVENITY® were arthralgia and headache.

EVENITY® is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

PI

Please scan the QR code or visit www.evenity.com/PI for EVENITY® full Prescribing Information, including Boxed Warning and Medication Guide.

Reference: 1. EVENITY® (romosozumab-aqqg) prescribing information, Amgen.

AMGEN®

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