Romosozumab (Evenity®)

Romosozumab is a monoclonal antibody prescribed to treat postmenopausal osteoporosis in patients who are at high risk for fracture, or in patients whom other therapy has failed or cannot be taken. Romosozumab inhibits sclerostin, a regulatory factor in the metabolism of bone. It increases bone formation, in contrast to bisphosphonates, to reduce risk for fractures.

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Patient Support Program

FDA-Approved Indications and Dosing in Rheumatology

Romosozumab is indicated for:

- Treatment of postmenopausal osteoporosis patients who are at high fracture risk.

Subcutaneous Dosing

- Postmenopausal osteoporosis: 210mg subcutaneously once monthly for up to 12 months. Each dose is given as two separate 105mg injections administered one after another.
- Calcium and Vitamin D supplements are also recommended while receiving intravenous romosozumab, and can be obtained over-the-counter as well as from food rich in these nutrients.

Contraindications

Hypocalcemia and known hypersensitivity to romosozumab

Warnings and Precautions

1. Major Adverse Cardiac Events (MACE): Monitor for symptoms of MI and stroke and seek prompt medical attention if symptoms occur
2. Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria. Discontinue if a clinically significant allergic reaction occurs
3. Hypocalcemia: Adequately supplement calcium and vitamin D during treatment
4. Osteonecrosis of the Jaw: Monitor for symptoms. Consider discontinuation of therapy based on benefit-risk assessment.
5. Atypical Femoral Fracture: Evaluate new or unusual thigh, hip, or groin pain to rule out an incomplete femur fracture

Adverse Reactions (≥ 5%)

Arthralgia and headache

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Medication Strength and Preparations

- Supplied as 105 mg/1.17 mL single-use prefilled syringe
- 2 syringes are required for full dose

Medication Administration and Storage

- Store between 2°C to 8°C in the original cartons, protected from light

Subcutaneous Administration:

- Should be administered by healthcare professional
- Always hold the prefilled syringes by the syringe barrel to remove the syringe from the tray
- Remove 2 prefilled syringes from refrigerator at least 30 minutes prior to injection, do not warm in any other way
- Choose two different injections sites, at least 2 inches apart, rotate injection sites each month. Avoid areas that are tender, bruised, scarred or with stretch marks.
- Solutions should appear clear to opalescent, colorless to light yellow, do not use if cloudy, discolored or contains any articulate matter.
- Do not use syringe if any part appears cracked or broken, the gray needle cap is missing or not securely attached or the expiration date has passed
- Administer subcutaneously into the abdomen (avoiding 2-inch area around navel), thigh or outer area of the upper arm.
- Immediately dispose of syringe and needle into sharps container
- Monitor for signs and symptoms of hypocalcemia, especially in patients predisposed to hypocalcemia (severe renal impairment, thyroid/parathyroid surgery, malabsorption syndromes, hypoparathyroidism); routine oral exam (prior to treatment); dental exam if risk factors for ONJ; monitor for signs/symptoms of hypersensitivity. Bone mineral density should be monitored for effectiveness.

Note: If a dose is missed, reschedule injection administration as soon as possible. Schedule subsequent injections every month from the date of last injection.

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