Emgality (galcanezumab-gnlm)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Emgality
- **Generic name:** Galcanezumab-gnlm
- **Pharmacological class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 120mg/mL; soln for SC inj; preservative-free
- **Manufacturer:** Eli Lilly
- **How supplied:** Single-dose prefilled pen—1, 2; Single-dose prefilled syringe—1, 2
- **Legal Classification:** Rx

Emgality

Indication

- Prophylaxis of migraine

Dosage & Administration

- Give by **SC inj** into abdomen, thigh, back of upper arm, or buttocks
- Initially 240mg loading dose (given as 2 consecutive 120mg inj), followed by 120mg monthly

Considerations for Special Populations

- **Pregnancy:** No adequate data on developmental risks in pregnant women
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed infant
- **Pediatric:** Not established
- **Elderly:** Insufficient number of patients studied

Warnings/Precautions

- Discontinue if serious or severe hypersensitivity reaction occurs; treat appropriately

Adverse Reactions

- Injection site reactions (eg, pain, erythema, pruritus)
- Hypersensitivity reactions

Mechanism of Action

- Galcanezumab-gnlm is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor

Clinical Studies

- Emgality was evaluated in 3 multicenter, randomized, double-blind, placebo-controlled studies, in patients 18 to 65 years old, as a preventative treatment of episodic or chronic migraine
  - **Study 1** (6 months; episodic migraine): N=858
  - **Study 2** (6 months; episodic migraine): N=915
  - **Study 3** (3 months; chronic migraine): N=1113

Clinical Studies

- Patients were randomized to receive once-monthly SC inj of Emgality 120mg, 240mg, or placebo
- **Primary efficacy endpoint** was the mean change from baseline in the number of monthly migraine headache over the treatment period

Clinical Studies

- Emgality 120mg demonstrated statistically significant improvements for efficacy endpoints vs placebo over the treatment period
  - **Study 1:** -4.7 days vs -2.8 days (*P* <.001)
  - **Study 2:** -4.3 days vs -2.3 days (*P* <.001)
  - **Study 3:** -4.8 days vs -2.7 days (*P* <.001)

Clinical Studies

- A greater proportion of patients reached ≥50% reduction in the number of monthly migraine headache days with Emgality vs placebo
  - **Study 1:** 62% vs 39% (*P* <.001)
  - **Study 2:** 59% vs 36% (*P* <.001)
  - **Study 3:** 28% vs 15% (*P* <.001)

Clinical Studies

- Emgality 240mg showed no additional benefit over Emgality 120mg for all studies

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/emgality/drug/34889/