Aimovig (erenumab-aooe)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Aimovig
- **Generic name:** Erenumab-aooe
- **Pharmacological class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 70mg/mL; soln for SC inj; preservative-free
- **Manufacturer:** Amgen
- **How supplied:** Single-dose prefilled SureClick autoinjectors—1, 2; Single-dose prefilled syringes—1, 2
- **Legal Classification:** Rx

Indications

- For the **preventive treatment of migraine** in adults

Aimovig

Dosage & Administration

- Give by **SC inj** into abdomen, thigh, or upper arm
- 70 mg once monthly
- Some patients may benefit from 140 mg (given as 2 consecutive 70 mg inj) once monthly

Considerations for Special Populations

- **Pregnancy:** No adequate data on developmental risk
- **Nursing mothers:** Consider benefits with mother's need and potential adverse effects on infant
- **Pediatric:** Not established
- **Elderly:** Caution with dose selection
- **Renal impairment:** Severe renal impairment (<30mL/min/1.73 m^2): not studied

Warnings/Precautions

- **Do not** inject into tender, bruised, red, or hard areas
- Latex allergy

Adverse Reactions

- Injection site reactions
- Constipation
- Cramps
- Muscle spasms

Mechanism of Action

- **Erenumab-aooe**, a human immunoglobulin G2 (IgG2) monoclonal antibody, binds to the calcitonin gene-related peptide (CGRP) receptor and antagonizes CGRP receptor function

Clinical Studies

- **Study 1** (N=955) was a randomized, multi-center, 6-month, placebo-controlled, double-blind study that enrolled patients with a history of episodic migraine (4 to 14 migraine days per month)

Clinical Studies

- Patients were randomized to Aimovig 70mg, Aimovig 140mg, or placebo as SC injection once monthly for 6 months
- Acute headache treatments were allowed, including migraine-specific medications and NSAIDs

Clinical Studies

- The **primary efficacy endpoint** was the change from baseline in mean monthly migraine days (MMD) over months 4 to 6

Clinical Studies

- At the end of 6 months, the change in MMD from baseline was:
  - Aimovig 70mg: -3.2 days (*P* <.001)
  - Aimovig 140mg: -3.7 days (*P* <.001)
  - Placebo: -1.8 days

Clinical Studies

- **Study 2** (N=577) was a randomized, multi-center, 3-month, placebo-controlled, double-blind study that enrolled patients with a history of episodic migraine (4 to 14 migraine days per month)

Clinical Studies

- Patients were randomized to receive either Aimovig 70mg or placebo as SC injection once monthly for 3 months
- Acute headache treatments were allowed, including migraine-specific medications and NSAIDs

Clinical Studies

- The **primary efficacy endpoint** was the change from baseline in MMD at month 3

Clinical Studies

- At the end of 3 months, the change in MMD from baseline was:
  - Aimovig 70mg: -2.9 days (*P* <.001)
  - Placebo: -1.8 days

Clinical Studies

- **Study 3** (N=667) was a randomized, multi-center, 3-month, placebo-controlled, double-blind study that enrolled patients with a history of chronic migraine (≥15 headache days per month with ≥8 migraine days per month) with or without aura

Clinical Studies

- Patients were randomized to Aimovig 70mg, Aimovig 140mg, or placebo as SC injection once monthly for 3 months

Clinical Studies

- The **primary efficacy endpoint** was the change from baseline in MMD at month 3

Clinical Studies

- At the end of 3 months, the change in MMD from baseline was:
  - Aimovig 70mg: -6.6 days (*P* <.001)
  - Aimovig 140mg: -6.6 days (*P* <.001)
  - Placebo: -4.2 days

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/aimovig/drug/34835/