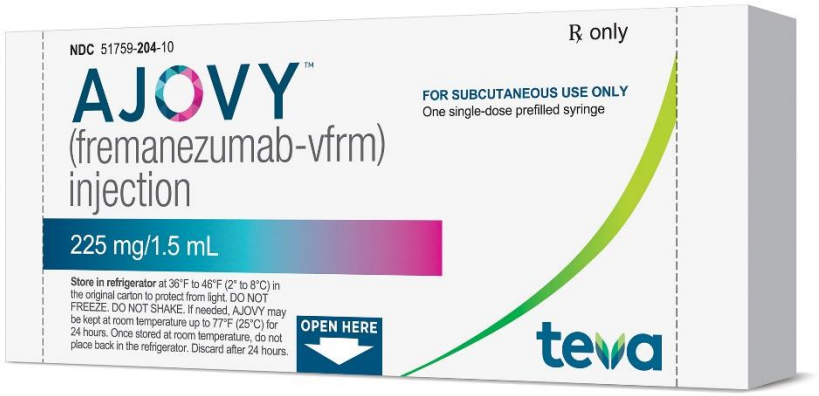
Ajovy (fremanezumab-vfrm)



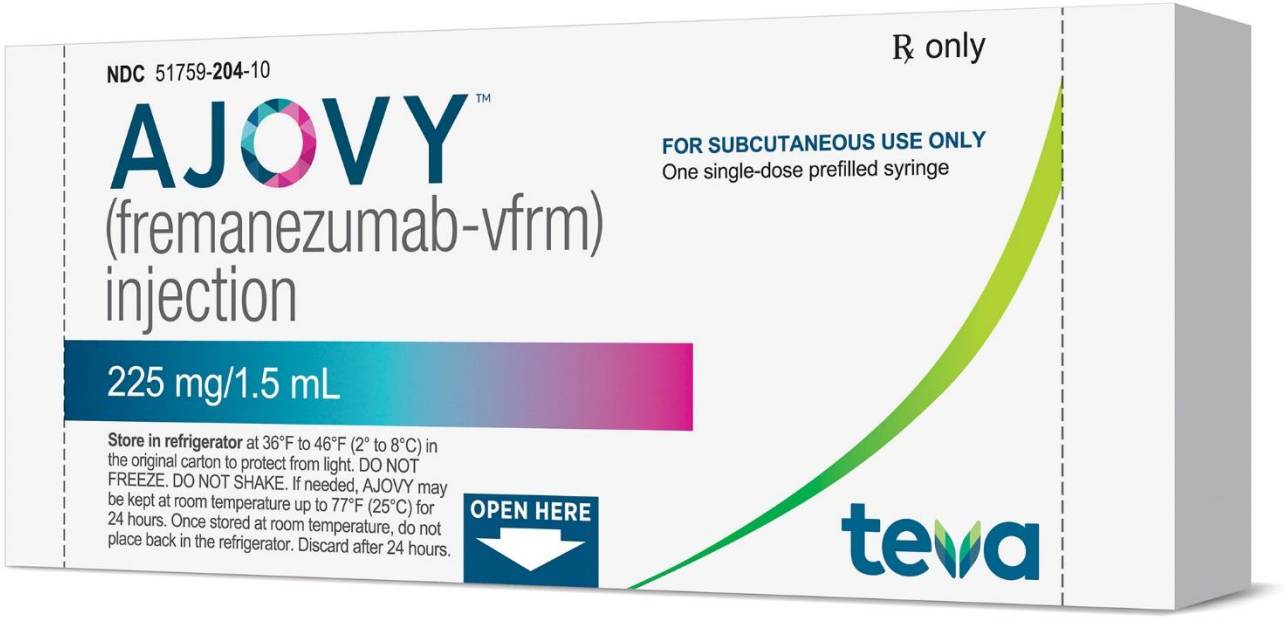
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Ajovy
- **Generic name:** Fremanezumab-vfrm
- **Pharmacological class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 225mg/1.5mL solution for subcutaneous injection; preservative-free
- **Manufacturer:** Teva Pharmaceuticals
- **How supplied:** Single-dose prefilled syringe—1
- **Legal Classification:** Rx

Ajovy


NDC 51759-204-10
℞ only
AJOVY™
(fremanezumab-vfrm)
injection
225 mg/1.5 mL
FOR SUBCUTANEOUS USE ONLY
One single-dose prefilled syringe
Store in refrigerator at 36°F to 46°F (2° to 8°C) in the original carton to protect from light. DO NOT FREEZE. DO NOT SHAKE. If needed, AJOVY may be kept at room temperature up to 77°F (25°C) for 24 hours. Once stored at room temperature, do not place back in the refrigerator. Discard after 24 hours.
OPEN HERE
teva

Indication

- Prophylaxis of migraine

Dosage & Administration

- Give by subcutaneous injection into abdomen, thigh, or upper arm
- 225mg monthly or 675mg (given as 3 consecutive 225mg injections) every 3 months

Considerations for Special Populations

- **Pregnancy:** No adequate data on the developmental risk
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed infant
- **Pediatric:** Not established

Warnings/Precautions

- Do not inject into tender, bruised, red, or indurated areas
- Consider discontinuing if hypersensitivity reaction occurs

Adverse Reactions

- **Injection site reactions**
  - Pain
  - Induration
  - Erythema
- Hypersensitivity reactions

Mechanism of Action

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

Clinical Studies

- Ajovy was evaluated in 2 multicenter, randomized, 3-month, double-blind, placebo-controlled studies **(Study 1 and Study 2)**

Clinical Studies

- **Study 1** included adults with a history of episodic migraine (N=875) who experienced <15 headache days per month
- Patients were randomized to Ajovy 675mg every 3 months (quarterly), Ajovy 225mg monthly, or placebo monthly

Clinical Studies

- **Primary endpoint:**
  - Mean change from baseline in the monthly average number of migraine days during the 3-month treatment period
- **Change from baseline in the monthly average number of migraine days:**
  - **-3.7** days (Ajovy 225mg monthly) vs **-3.4** days (Ajovy 675mg quarterly) vs **-2.2** days (placebo)

Clinical Studies

- **Study 2** included adults with a history of chronic migraine (N=1130) who experienced ≥15 headache days per month
- Patients were randomized to Ajovy 675mg starting dose followed by 225mg monthly, Ajovy 675mg every 3 months (quarterly), or placebo monthly

Clinical Studies

- **Primary endpoint:**
  - Mean change from baseline in the monthly average number of headache days of at least moderate severity during the 3-month treatment period
- **Change from baseline in the monthly average number of headache days of at least moderate severity:**
  - **-4.6** days (Ajovy 225mg monthly) vs **-4.3** days (Ajovy 675mg quarterly) vs **-2.5** days (placebo)

Clinical Studies

- Both monthly and quarterly dosing regimens of Ajovy demonstrated statistically significant improvements for efficacy endpoints vs placebo

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/ajovy/drug/34876/