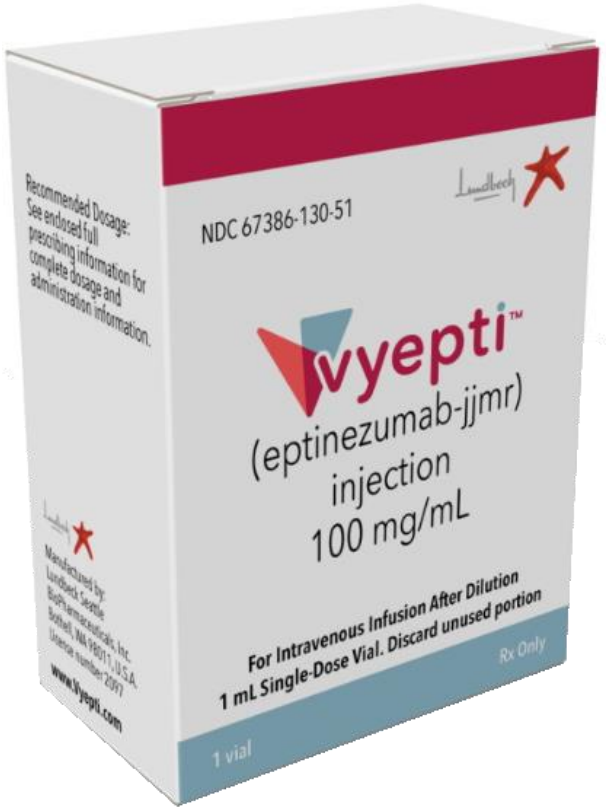
Vyepti (eptinezumab-jjmr)



NEW PRODUCT SLIDESHOW

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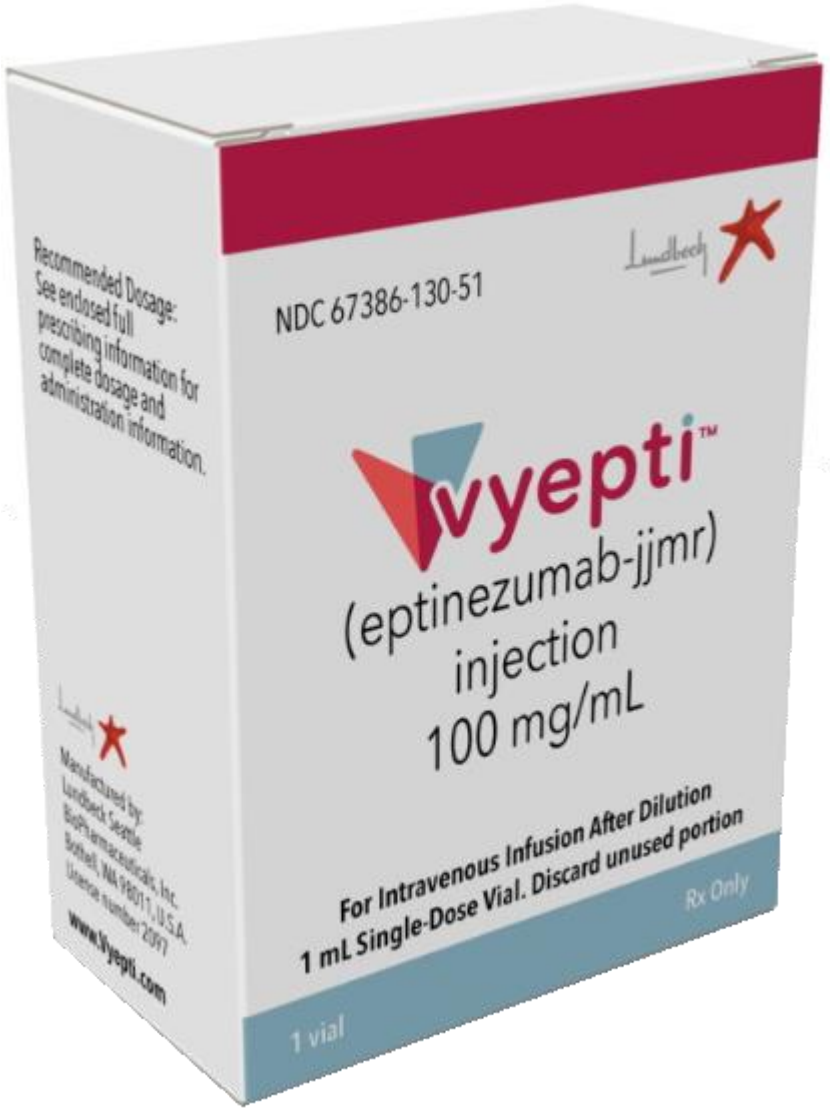
Introduction

- **Brand name:** Vyepti
- **Generic name:** Eptinezumab-jjmr
- **Pharmacologic class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 100mg/mL; per vial; solution for IV infusion after dilution; preservative-free
- **Manufacturer:** Lundbeck
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

Vyepti


Recommended Dosage:
See enclosed full prescribing information for complete dosage and administration information.
NDC 67386-130-51
vyepti™
(eptinezumab-jjmr)
injection
100 mg/mL
For Intravenous Infusion After Dilution
1 mL Single-Dose Vial. Discard unused portion
Rx Only
1 vial
Manufactured by:
Lundbeck Seattle BioPharmaceuticals, Inc.
Bothell, WA 98011, U.S.A.
License number 2097
www.Vyepti.com

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Indication

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

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Dosage and Administration

- Give by IV infusion over 30 minutes
- 100mg every 3 months; some patients may benefit from 300mg every 3 months
- Requires dilution prior to administration
- Following dilution, the solution must be infused within 8 hours

Considerations for Special Populations

- **Pregnancy:** no adequate data to evaluate drug-associated risk
- **Nursing mothers**: no data on presence in human milk
- **Pediatric**: safety, effectiveness not established
- **Geriatrics**: studies did not include sufficient numbers of patients aged 65 years and over to determine if response is different

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Warnings/Precautions

- Consider discontinuing if a **hypersensitivity reaction** occurs and treat appropriately
  - Most hypersensitivity reactions occurred during infusion and were not serious, but often led to discontinuation or required treatment
  - Serious hypersensitivity reactions may occur

Adverse Reactions

- **Most frequent (incidence ≥2% and 2% or greater than placebo)**: nasopharyngitis, hypersensitivity

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Mechanism of Action

- Eptinezumab-jjmr is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor
- CGRP is believed to play a key role in migraine pathophysiology

Pharmacokinetics

- Steady-state plasma concentration attained after the first dose with a once every 3-month dosing schedule
- Degraded by proteolytic enzymes into small peptides and amino acids
- Terminal elimination half-life approximately 27 days
- No dedicated studies were conducted to assess the effects of renal or hepatic impairment on pharmacokinetics

Clinical Trials

- Two placebo-controlled studies, both with 6-month double-blind periods
  - Study 1: patients with episodic migraine
  - Study 2: patients with chronic migraine
- Vyepti administered by IV infusion every 3 months
- Primary end point measured at 12 weeks

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Clinical Trials

Episodic Migraine Trial

- Study included adults with a history of episodic migraine (4 to 14 headache days per month, of which at least 4 were migraine days)
- 665 patients (222 for placebo; 221 for Vyepti 100mg; 222 for Vyepti 300mg)
- Patients were treated every 3 months for 12 months
- Concurrent acute migraine or headache meds, including migraine-specific drugs were allowed during the trial
- Median age: 39 years; 84% female; 84% white
- Mean migraine frequency at baseline was ~8.6 migraine days per month and was similar across the groups

Clinical Trials

- **Primary efficacy end point** was the change from baseline in mean monthly migraine days over Months 1-3

- **Secondary end points** included the percentages of patients with 50% or greater, and 75% or greater reductions from baseline in monthly migraine days over Months 1-3

Clinical Trials

- Vyepti demonstrated statistically significant improvements compared with placebo
- *Monthly migraine days (MMD)-Months 1-3*
  - **Change from baseline**: -3.9 with Vyepti 100mg (difference from placebo: -0.7; *P* = .018) and -4.3 with Vyepti 300mg (difference from placebo: -1.1; *P* <.001) vs -3.2 with placebo
- *≥50% MMD responders – Months 1-3*
  - **% Responders**: 49.8% with Vyepti 100mg (difference from placebo: 12.4%; *P* =.009) and 56.3% with Vyepti 300mg (difference from placebo: 18.9%; *P* <.001) vs 37.4% with placebo
- *≥75% MMD responders – Months 1-3*
  - **% Responders**: 22.2% with Vyepti 100mg (difference from placebo: 6.0%) and 29.7% with Vyepti 300mg (difference from placebo: 13.5%; *P* <.001) vs 16.2% with placebo

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Clinical Trials

Chronic Migraine Trial

- Study included adults with a history of chronic migraine (15 to 26 headache days per month, of which at least 8 were migraine days)
- A total of 1072 patients were randomized and received placebo (n=366), Vyepti 100mg (n=356), or Vyepti 300mg (n=350) every 3 months for 6 months
- Patients were allowed to use and to continue an established stable regimen of acute migraine or headache preventive medication
- Median age: 41 years; 88% female; 91% white
- Mean migraine frequency at baseline was ~16.1 migraine days per month and was similar across groups

Clinical Trials

- **Primary efficacy end point** was the change from baseline in mean monthly migraine days over Months 1-3

- **Secondary end points** included the percentages of patients with 50% or greater, and 75% or greater reductions from baseline in monthly migraine days over Months 1-3

Clinical Trials

- Vyepti demonstrated statistically significant improvements compared with placebo
- *Monthly migraine days (MMD)-Months 1-3*
  - **Change from baseline**: -7.7 with Vyepti 100mg (difference from placebo: -2.0; *P* < .001) and -8.2 with Vyepti 300mg (difference from placebo: -2.6; *P* <.001) vs -5.6 with placebo
- *≥50% MMD responders – Months 1-3*
  - **% Responders**: 57.6% with Vyepti 100mg (difference from placebo: 18.2%; *P* <.001) and 61.4% with Vyepti 300mg (difference from placebo: 22.1%; *P* <.001) vs 39.3% with placebo
- *≥75% MMD responders – Months 1-3*
  - **% Responders**: 26.7% with Vyepti 100mg (difference from placebo: 11.7%; *P* <.001) and 33.1% with Vyepti 300mg (difference from placebo: 18.1%; *P* <.001) vs 15.0% with placebo

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New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/vyepti/