vyepti®
(eptinezumab-jjmr)
100 mg/mL Injection for IV

VYEPTI is a prescription medicine used for the preventive treatment of migraine in adults.

say yep to the migraine-free days you deserve

Proven migraine prevention in clinical studies

Actor portrayal

IMPORTANT SAFETY INFORMATION

Do not receive VYEPTI if you have a known allergy to eptinezumab-jjmr or its ingredients.

VYEPTI may cause serious side effects such as:

- **Allergic reactions.** Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction: rash; swelling of your face, lips, tongue, or throat; trouble breathing; hives; or redness in your face.

Please see additional Important Safety Information throughout and the accompanying full **Prescribing Information** and **Patient Information**.

Visit vyepti.com for more information.

How migraine can impact your life

- Inability to make or stick to plans
- Struggling to keep up with daily responsibilities
- Barely making it through the day, let alone enjoying life

"Migraine has impacted many aspects of my life. When I was first diagnosed, I lost a lot of friends because they didn't understand what I was going through."

Nicole,
VYEPTI patient

VYEPTI patients featured in this brochure were compensated for their time.

Individual results may vary.

vyepti®
(eptinezumab-jjmr)
100 mg/mL Injection for IV

Do less to manage migraine

30 min
4X A YEAR

VYEPTI helps prevent migraine attacks with **just four 30-minute IV treatments a year** (every 3 months) given by a healthcare provider.

100% delivery

As an IV infusion, 100% of the medication is delivered into your bloodstream, **so it can get right to work**.

Lasts 3 months

VYEPTI was purposefully designed as an IV infusion to start working fast and **last through month 3** after each infusion.

IMPORTANT SAFETY INFORMATION

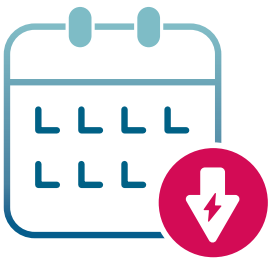
VYEPTI may cause serious side effects such as:

- **Constipation with serious complications.** Severe constipation can happen. In some cases, people have been hospitalized. Contact your healthcare provider if you have severe constipation or constipation with severe or constant belly pain, vomiting, swelling of belly, or bloating.

Please see additional Important Safety Information throughout.

People on VYEPTI had fewer migraine days

What can people expect with VYEPTI?



In a study of people with chronic migraine

People who averaged 16 migraine days a month receiving VYEPTI* had an average of

8 ***fewer*** **migraine days a month**

over 3 months, vs 6 with placebo

In a study of people with episodic migraine

People who averaged 9 migraine days a month receiving VYEPTI* had an average of

4 ***fewer*** **migraine days a month**

over 3 months, vs 3 with placebo

*VYEPTI 100 mg or 300 mg.

"Having more migraine-free days has made a ***big difference*** *in my life. I'm able to go to baseball games, concerts, enjoy my family, and little things like reading."*

Florian,
VYEPTI patient

Individual results may vary.

SEE MORE STUDY RESULTS ▶

IMPORTANT SAFETY INFORMATION

VYEPTI may cause serious side effects such as:

- **High blood pressure.** High blood pressure or worsening of high blood pressure can happen. Contact your healthcare provider if you have an increase in blood pressure.
- **Raynaud's phenomenon.** A type of circulation problem (Raynaud's phenomenon) can worsen or happen. Contact your healthcare provider if you have symptoms such as your fingers or toes feeling numb, cool, or painful, or changing color from pale to blue to red.

Please see additional Important Safety Information throughout.

A treatment with a proven safety profile

The most common side effects of VYEPTI in clinical studies were stuffy nose and scratchy throat, and allergic reactions.

Less than 2% of more than 1100 people stopped receiving VYEPTI due to side effects in clinical studies.

Long-term safety

Side effects were similar when the safety of VYEPTI 300 mg, given every 12 weeks, was tested over 2 years in an additional study of 128 adults with chronic migraine. Discontinuation due to side effects was 6%. Everyone in the study knew they were receiving VYEPTI, and it was not compared with placebo, both of which could have impacted the results.

VYEPTI can also cause serious side effects such as allergic reactions, constipation with serious complications, high blood pressure, and Raynaud's phenomenon (a type of circulation problem).

IMPORTANT SAFETY INFORMATION

Before starting VYEPTI, tell your healthcare provider about all your medical conditions, including if you have high blood pressure; circulation problems in your fingers and toes; are pregnant or plan to become pregnant; or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including any prescription and over-the-counter medicines, vitamins, or herbal supplements.

Please see additional Important Safety Information throughout.

Say yep to potential savings with copay assistance

YOU MAY PAY AS LITTLE AS **$0** PER VYEPTI INFUSION*

For eligible, commercially insured patients

Offer includes up to $200 in administration out-of-pocket fees per treatment and renews every year.

*For eligible patients with commercial insurance. Your out-of-pocket cost may vary depending on your dose, insurance coverage, and eligibility. Talk to your insurance provider for specific information about your prescription coverage. Offer includes 100 mg and up to 300 mg doses. Eligibility criteria and program maximums apply. This offer is NOT available for people enrolled in Medicare, Medicaid, or any other government healthcare program. Patients residing in MA and RI are not eligible for copay assistance for product administration costs. View full terms and conditions at vyeptisavings.com.

Know you're supported

Not sure if you qualify for copay assistance? Get info about the VYEPTI CONNECT® support program on our website for help understanding your insurance coverage.

LEARN MORE ABOUT FINANCIAL ASSISTANCE ▶

"I feel great after my infusion. VYEPTI helps me go on with my life."

Jennifer, VYEPTI patient

Individual results may vary.

IMPORTANT SAFETY INFORMATION

The most common side effects of VYEPTI include stuffy nose and scratchy throat, and allergic reactions. These are not all the possible side effects of VYEPTI. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Please see additional Important Safety Information throughout.

Have questions about VYEPTI?

Ask a nurse

Registered nurses are accessible by phone—whether you have a VYEPTI prescription or are considering it as a treatment option. Get answers to your questions by talking to a real nurse.

Call 833-4-VYEPTI (833-489-3784), option 2 during normal business hours to connect live with a nurse.

Get your VYEPTI infusion at the best location for you

When it comes to infusion locations, you have options, including those within the VYEPTI Infusion Network. Talk with your doctor and insurance to find a location that works for you.

- **Your doctor's office**
- **An infusion center**
- **A hospital outpatient clinic**
- **Your home**

FIND AN INFUSION LOCATION ▶

Ask a doctor if it may be time to

say **yep** to **vyepti®**

(eptinezumab-jjmr)

100 mg/mL Injection for IV

If migraine is still impacting your life, **don't wait to share your experience with your doctor.** Partnering with your doctor can help you find out if VYEPTI might be right for you.

Did you know?

77% of people in a survey of 1,100 people with migraine *(who also had a mental health condition)* **worried about the stigma of migraine and mental health.** In fact, many were hesitant to discuss the issue with their doctor.*

*The Migraine and Mental Health Connection Survey (conducted online, 2022), consisting of 1,100 people with migraine who also identified as having a mental health condition.

Ready to start the conversation?

Think about the answers to these questions before your next doctor's visit.

1. **What types of activities or events are impacted by migraine?**

2. **How many days a month are "crystal clear" and not impacted by migraine in any way?**

3. **In the last 3 months, have you been having more migraine attacks?**

4. **In the last 3 months, have you been taking more medication to stop migraine attacks?**

START THE CONVERSATION ABOUT VYEPTI WITH YOUR DOCTOR

vyepti®
(eptinezumab-jjmr)
100 mg/mL Injection for IV

VYEPTI is a prescription medicine used for the preventive treatment of migraine in adults.

Shouldn't you get the **migraine-free days** you deserve?

VYEPTI is proven to reduce monthly migraine days and keep working for 3 months after treatment.

SIGN UP FOR ACCESS TO MORE INFO ABOUT VYEPTI, INSURANCE, AND MORE

Questions about VYEPTI?
Call us for support at **833-4-VYEPTI (833-489-3784)**, option 2.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

Please see Important Safety Information throughout and the accompanying full **Prescribing Information** and **Patient Information**.

Visit vyepti.com for more information.

Lundbeck

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VYEPTI safely and effectively. See full prescribing information for VYEPTI.

VYEPTI® (eptinezumab-jjmr) injection, for intravenous use
Initial U.S. Approval: 2020

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.2) 06/2026

----------INDICATIONS AND USAGE----------
VYEPTI is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults (1)

----------DOSAGE AND ADMINISTRATION----------
- Must dilute before use. For intravenous infusion only (2.1, 2.2)
- Recommended dosage is 100 mg as an intravenous infusion over approximately 30 minutes every 3 months. Some patients may benefit from a dosage of 300 mg every 3 months (2.1, 2.3)
- Dilute only in 100 mL of 0.9% Sodium Chloride Injection (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: 100 mg/mL solution in a single-dose vial (3)

----------CONTRAINDICATIONS----------
VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients (4)

----------WARNINGS AND PRECAUTIONS----------
- Hypersensitivity Reactions: If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and initiate appropriate therapy (5.1)
- Constipation with Serious Complications: Serious complications of constipation may occur (5.2)
- Hypertension: New-onset or worsening of pre-existing hypertension may occur (5.3)
- Raynaud's Phenomenon: New-onset or worsening of pre-existing Raynaud's phenomenon may occur (5.4)

----------ADVERSE REACTIONS----------
The most common adverse reactions (≥2% and 2% or greater than placebo) were nasopharyngitis and hypersensitivity (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Lundbeck at 1-800-455-1141 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 06/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VYEPTI is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The recommended dosage is 100 mg administered by intravenous infusion every 3 months. Some patients may benefit from a dosage of 300 mg administered by intravenous infusion every 3 months.

2.2 Dilution Instructions

VYEPTI requires dilution prior to administration. Dilute only in 100 mL 0.9% Sodium Chloride Injection. The infusion bags must be made of polyvinyl chloride (PVC), polyethylene (PE), or polyolefin (PO). Use appropriate aseptic technique when preparing VYEPTI solution for intravenous infusion. VYEPTI single-dose vials contain no preservative; discard unused portion remaining in the vial.

Dilution

100 mg dose:

To prepare the solution, withdraw 1 mL of VYEPTI from a single-dose vial using a sterile needle and syringe. Inject the 1 mL content into a 100 mL bag of 0.9% Sodium Chloride Injection.

300 mg dose:

To prepare the solution, withdraw 1 mL of VYEPTI from each of 3 single-dose vials using a sterile needle and syringe. Inject the resulting 3 mL content into a 100 mL bag of 0.9% Sodium Chloride Injection.

Storage and Handling of Diluted Product

Gently invert the VYEPTI solution to mix completely. Do not shake. Following dilution, VYEPTI solution must be infused within 8 hours. During this time, VYEPTI solution should be stored at room temperature, 20°C to 25°C (68°F to 77°F). Do not freeze.

2.3 Infusion Administration Instructions

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the liquid contains visible particulate matter or is cloudy or discolored *[see Dosage Forms and Strengths (3)]*.

No other medications should be administered through the infusion set or mixed with VYEPTI. VYEPTI is for intravenous infusion only; infuse over approximately 30 minutes. Do not administer VYEPTI as an intravenous push or bolus injection. Use an intravenous infusion set with a 0.2 micron or 0.22 micron in-line or add-on sterile filter. After the infusion is complete, flush the line with 20 mL of 0.9% Sodium Chloride Injection.

3 DOSAGE FORMS AND STRENGTHS

VYEPTI is a clear to slightly opalescent, colorless to brownish-yellow solution available as follows:

- Injection: 100 mg/mL in a single-dose vial

4 CONTRAINDICATIONS

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients in VYEPTI. Reactions have included anaphylaxis and angioedema *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including angioedema, urticaria, facial flushing, dyspnea, and rash, have occurred with VYEPTI in clinical trials and in the postmarketing setting. Most hypersensitivity reactions occurred during infusion and were not serious, but often led to discontinuation or required treatment. Serious hypersensitivity reactions may occur. Cases of anaphylaxis have been reported in the postmarketing setting**.** If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and institute appropriate therapy *[see Contraindications (4) and Patient Counseling Information (17)]*.

5.2 Constipation with Serious Complications

Constipation with serious complications has been reported following the use of monoclonal antibody CGRP antagonists, including VYEPTI, in the postmarketing setting. There were cases with monoclonal antibody CGRP antagonists that required hospitalization, including cases where surgery was necessary. In a majority of these cases, the onset of constipation was reported after the first dose; however, patients have also presented with constipation later on in treatment. The monoclonal antibody CGRP antagonist was discontinued in many of the reported cases of constipation with serious complications.

Monitor patients treated with VYEPTI for severe constipation and manage as clinically appropriate. The concurrent use of medications that reduce gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

5.3 Hypertension

Development of hypertension and worsening of pre-existing hypertension have been reported following the use of CGRP antagonists, including VYEPTI, in the postmarketing setting. Some of the patients who developed new-onset hypertension had risk factors for hypertension. There were cases requiring initiation of pharmacological treatment for hypertension, and in some cases hospitalization. Hypertension may occur at any time during treatment, but was most frequently reported within 7 days of therapy initiation. The CGRP antagonist was discontinued in many of the reported cases.

Monitor patients treated with VYEPTI for new-onset hypertension or worsening of pre-existing hypertension, and consider whether discontinuation of VYEPTI is warranted if evaluation fails to establish an alternative etiology or blood pressure is inadequately controlled.

5.4 Raynaud’s Phenomenon

Development of Raynaud’s phenomenon and recurrence or worsening of pre-existing Raynaud’s phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists. In reported cases with monoclonal antibody CGRP antagonists, symptom onset occurred a median of 71 days following dosing. Many of the cases reported serious outcomes, including hospitalizations and disability, generally related to debilitating pain. In most reported cases, discontinuation of the CGRP antagonist resulted in resolution of symptoms.

VYEPTI should be discontinued if signs or symptoms of Raynaud’s phenomenon develop, and patients should be evaluated by a healthcare provider if symptoms do not resolve. Patients with a history of Raynaud’s phenomenon should be monitored for, and informed about the possibility of, worsening or recurrence of signs and symptoms.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*
- Constipation with Serious Complications *[see Warnings and Precautions (5.2)]*
- Hypertension *[see Warnings and Precautions (5.3)]*
- Raynaud's Phenomenon *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of VYEPTI was evaluated in 2076 patients with migraine who received at least one dose of VYEPTI, representing 1615 patient-years of exposure; of these, 1524 patients were exposed to 100 mg or 300 mg. Across all doses, 1872 patients were exposed for at least 6 months and 991 patients were exposed for 12 months. In the placebo-controlled clinical studies (Study 1 and Study 2) of 1372 patients, 579 patients received at least one dose of VYEPTI 100 mg, 574 patients received at least one dose of VYEPTI 300 mg, and 588 patients received placebo *[see Clinical Studies (14)]*. Approximately 86% were female, 89% were white, and the mean age was 40.4 years at study entry.

The most common (incidence at least 2% and at least 2% greater than placebo) adverse reactions in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity.

Table 1 summarizes the adverse reactions that occurred during Study 1 and Study 2.

Table 1. Adverse Reactions Occurring with an Incidence of at Least 2% for VYEPTI and at Least 2% Greater than Placebo in Studies 1 and 2

Adverse Reactions	VYEPTI 100 mg N=579 %	VYEPTI 300 mg N=574 %	Placebo N=588 %
Nasopharyngitis	6	8	6
Hypersensitivity reactions*	1	2	0

* Hypersensitivity reactions includes multiple related adverse event terms, such as hypersensitivity, pruritus, and flushing/hot flush that occurred on the day of dosing.

In Study 1 and Study 2, 1.9% of patients treated with VYEPTI discontinued treatment because of adverse reactions *[see Warnings and Precautions (5.1)]*.

In Study 3, the safety profile observed in 480 patients who were randomized and treated (238 to VYEPTI 100 mg and 242 to placebo) was consistent with the safety profile observed in the two pivotal placebo-controlled studies with VYEPTI (Study 1 and Study 2).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of VYEPTI. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Gastrointestinal Disorders: Constipation *[see Warnings and Precautions (5.2)]*

General Disorders and Administration Site Conditions: Fatigue
Immune System Disorders: Anaphylaxis *[see Contraindications (4) and Warnings and Precautions (5.1)]*
Vascular Disorders: Hypertension *[see Warnings and Precautions (5.3)]*, Raynaud's phenomenon *[see Warnings and Precautions (5.4)]*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYEPTI during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-855-810-8549 or by contacting the company at www.vyeptipregnancyregistry.lundbeck.com.

Risk Summary

There are no adequate data on developmental risks associated with the use of VYEPTI in pregnant women.

No adverse developmental effects were observed following administration of eptinezumab-jjmr to pregnant animals at doses greater than those used clinically *[see Data]*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively. The estimated rate of major birth defects (2.2%-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly to female rats and rabbits by intravenous injection throughout organogenesis, no adverse effects on embryofetal development were observed. The higher dose tested (150 mg/kg) is 30 times the maximum recommended human dose (MRHD) of 300 mg, on a body weight basis (mg/kg).

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly to female rats throughout pregnancy and lactation, no adverse effects on pre- and postnatal development were observed. The higher dose tested (150 mg/kg) is 30 times the MRHD, on a mg/kg basis.

8.2 Lactation

Risk Summary

There are no data on the presence of eptinezumab-jjmr in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYEPTI and any potential adverse effects on the breastfed infant from VYEPTI or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of VYEPTI did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

11 DESCRIPTION

Eptinezumab-jjmr is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. Eptinezumab-jjmr has an approximate molecular weight of 143 kD. Eptinezumab-jjmr is produced in *Pichia pastoris* yeast cells by recombinant DNA technology.

VYEPTI (eptinezumab-jjmr) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to brownish-yellow solution, for intravenous infusion. VYEPTI is supplied as a 100 mg/mL single-dose vial. Each mL contains 100 mg eptinezumab-jjmr formulated in L-histidine (1 mg), L-histidine hydrochloride monohydrate (2.8 mg), polysorbate 80 (0.15 mg), sorbitol (40.5 mg), and Water for Injection, USP, at a pH of 5.8.

12 CLINICAL PHARMACOLOGY

12.1 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.

12.2 Pharmacodynamics

The relationship between the pharmacodynamic activity and the mechanism(s) by which eptinezumab-jjmr exerts its clinical effects is unknown.

12.3 Pharmacokinetics

Eptinezumab-jjmr exhibits linear pharmacokinetics and exposure increases proportionally with doses from 100 mg to 300 mg after intravenous administration. Steady-state plasma concentration is attained after the first dose with a once every 3-month dosing schedule.

Distribution

The central volume of distribution (Vc) for eptinezumab-jjmr is approximately 3.7 liters.

Metabolism & Elimination

Eptinezumab-jjmr is expected to be degraded by proteolytic enzymes into small peptides and amino acids.

The apparent clearance of eptinezumab-jjmr was 0.006 L/h, and the terminal elimination half-life was approximately 27 days.

Specific Populations

A population pharmacokinetic analysis assessing the effects of age, race, sex, and body weight did not suggest any clinically significant impact of these covariates on eptinezumab exposures.

Patients with Renal or Hepatic Impairment

No dedicated studies were conducted to assess the effects of renal or hepatic impairment on the pharmacokinetics of eptinezumab-jjmr. However, hepatic or renal impairment is not expected to affect the pharmacokinetics of eptinezumab-jjmr. A population pharmacokinetic analysis of integrated data from eptinezumab-jjmr clinical studies did not reveal clinically significant impact on pharmacokinetics of patients with hepatic or renal impairment.

Drug Interaction Studies

P450 Enzymes

Eptinezumab-jjmr is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Sumatriptan

The co-administration of a single dose of 300 mg eptinezumab-jjmr administered as an intravenous infusion (over a period of 1 hour ± 15 min) with a single dose of 6 mg sumatriptan administered subcutaneously did not significantly influence the pharmacokinetics of eptinezumab-jjmr or sumatriptan.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of eptinezumab-jjmr.

In patients receiving VYEPTI 100 mg or 300 mg every 3 months, the incidence of anti-eptinezumab-jjmr antibody development in Study 1 (up to 56 weeks) was 20.6% (92/447), and 41.3% (38/92) of those patients developed anti-eptinezumab-jjmr neutralizing antibodies. In Study 2 (up to 32 weeks), the incidence of anti-eptinezumab-jjmr antibody development was 18.3% (129/706), and 34.9% (45/129) of those patients developed anti-eptinezumab-jjmr neutralizing antibodies. In an open-label study with 84 weeks of treatment, 18% (23/128) of patients developed anti-eptinezumab-jjmr antibodies, and 39% (9/23) of those patients developed anti-eptinezumab-jjmr neutralizing antibodies.

Although the results from both studies showed no clear evidence of an impact from development of anti-eptinezumab-jjmr antibodies, including neutralizing antibodies, on the safety and efficacy profiles of VYEPTI, the available data are too limited to make definitive conclusions.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

The carcinogenic potential of eptinezumab-jjmr has not been assessed.

Mutagenesis

Genetic toxicology studies of eptinezumab-jjmr have not been conducted.

Impairment of Fertility

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly by intravenous injection to male and female rats prior to and during mating and continuing in females to gestation day 3-4, no adverse effects on fertility were observed. The higher dose tested (150 mg/kg) is 30 times the maximum recommended human dose of 300 mg, on a body weight basis (mg/kg).

14 CLINICAL STUDIES

The efficacy of VYEPTI was evaluated in three randomized, multicenter, placebo-controlled double-blind studies that enrolled patients with episodic and chronic migraine who were eligible for preventive treatment of migraine. In Study 1, which included patients with episodic migraine, and Study 2, which included patients with chronic migraine, either 100 mg or 300 mg VYEPTI was administered by intravenous infusion every 3 months. In Study 3, 100 mg VYEPTI was

administered as a single intravenous infusion to patients with episodic or chronic migraine who were eligible for preventive migraine treatment and who had a concurrent migraine.

Study 1: Episodic Migraine

Study 1 (NCT02559895) included adults with a history of episodic migraine (4 to 14 headache days per month, of which at least 4 were migraine days). A total of 665 patients were randomized to receive placebo (N=222), 100 mg VYEPTI (N=221), or 300 mg VYEPTI (N=222) every 3 months for 12 months. Patients were allowed to use concurrent acute migraine or headache medications, including migraine-specific medications (i.e., triptans, ergotamine derivatives), during the trial.

The study excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days over Months 1-3. Secondary endpoints included the percentages of patients with 50% or greater, and 75% or greater reductions from baseline in monthly migraine days over Months 1-3.

Patients had a median age of 39 years (range: 18 to 71 years), 84% were female, and 84% were white. The mean migraine frequency at baseline was approximately 8.6 migraine days per month and was similar across treatment groups.

VYEPTI treatment demonstrated statistically significant improvements compared to placebo for the primary efficacy endpoint, as shown in Table 2; secondary endpoints are also summarized in Table 2.

Table 2. Efficacy Endpoint Results in Study 1

	VYEPTI 100 mg N=221	**VYEPTI 300 mg N=222**	**Placebo N=222**
Monthly Migraine Days (MMD) – Months 1-3			
Change from baseline	-3.9	-4.3	-3.2
Difference from placebo	-0.7	-1.1	
p-value	0.018	<0.001	
≥50% MMD responders – Months 1-3			
% Responders	49.8%	56.3%	37.4%
Difference from placebo	12.4%	18.9%	
p-value	0.009*	<0.001	
≥75% MMD responders – Months 1-3			
% Responders	22.2%	29.7%	16.2%
Difference from placebo	6.0%	13.5%	
p-value	NS**	<0.001	

* Nominal statistical significance
** NS = Not statistically significant

Figure 1 shows the mean change from baseline in average monthly migraine days in Study 1. Patients treated with VYEPTI at both doses had greater mean decreases from baseline in mean monthly migraine days over Months 1-3 compared to placebo-treated patients.

Figure 1. Change from Baseline in Monthly Migraine Days in Study 1

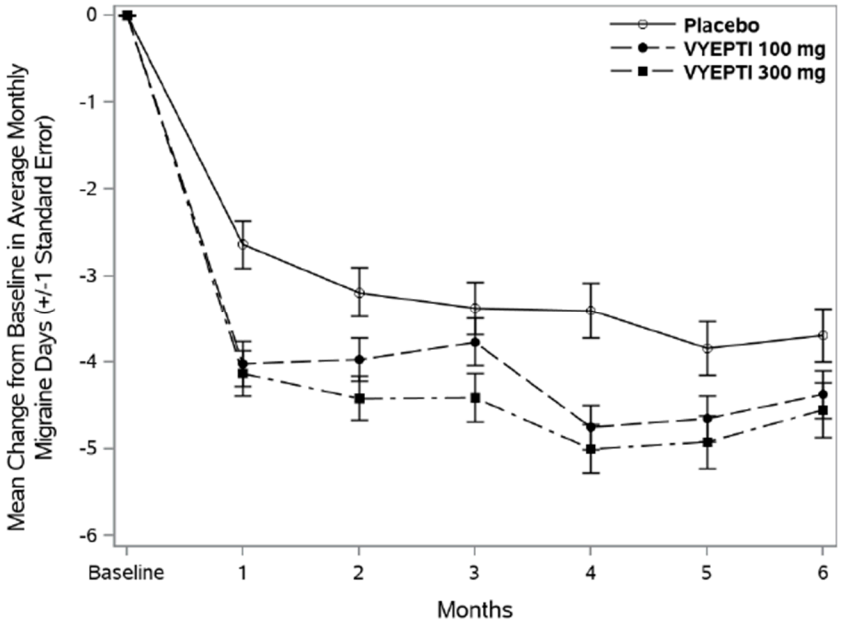


Figure 2 shows the distribution of change from baseline in mean monthly migraine days through Month 3 by treatment group in 2-day increments.

Figure 2. Distribution of Change from Baseline in Mean Monthly Migraine Days over Months 1 to 3 by Treatment Group in Study 1

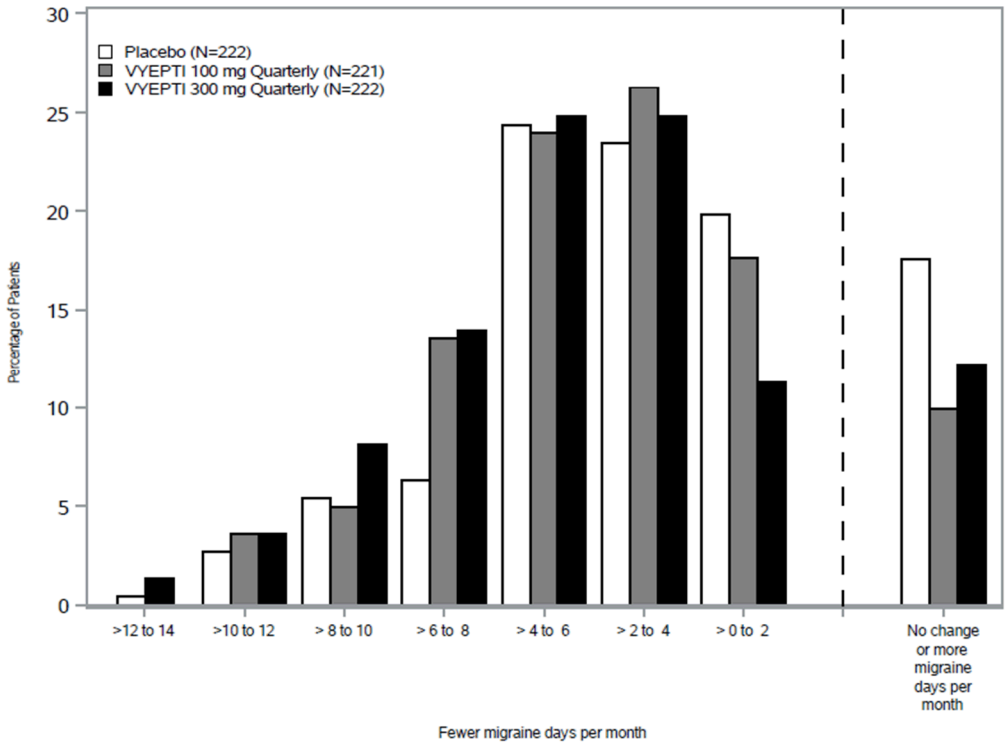
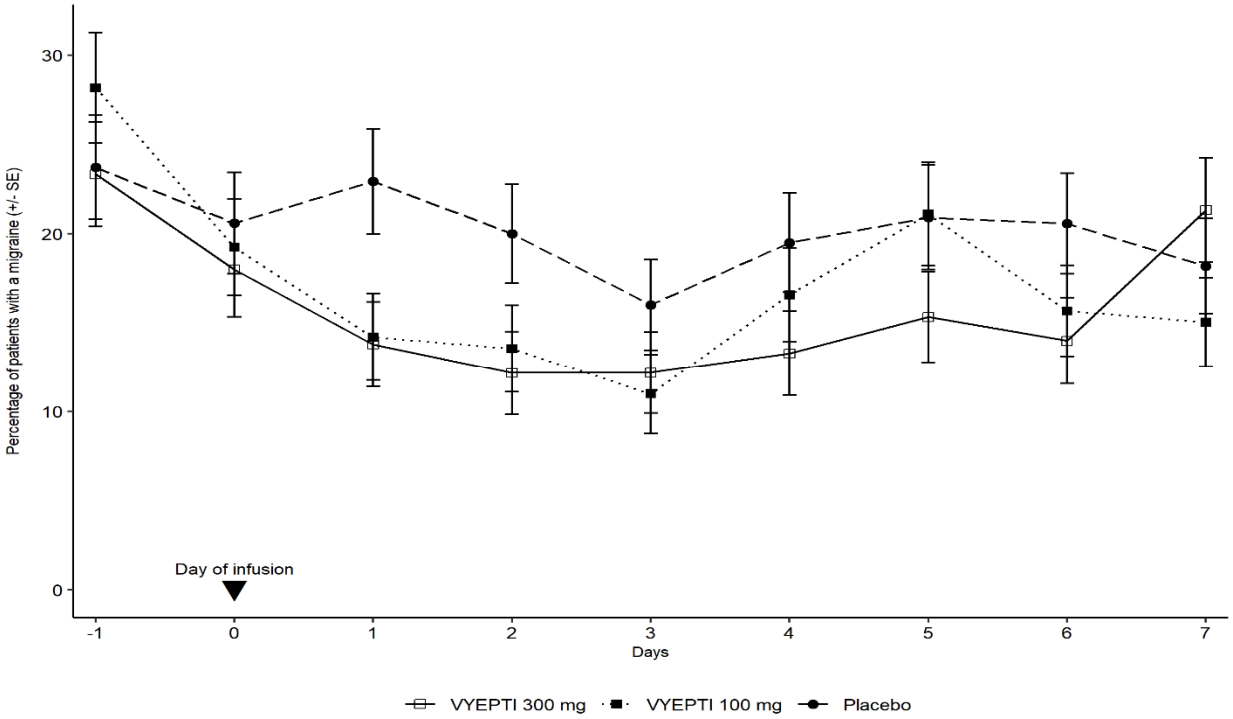


Figure 3 demonstrates that greater percentages of placebo-treated patients had migraines on most days during the first 7 days of treatment compared to VYEPTI-treated patients in Study 1.

Figure 3. Percentage of Patients with a Migraine from Day -1 (Day Prior to Infusion) to Day 7 in Study 1



Study 2: Chronic Migraine

Study 2 (NCT02974153) 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), 100 mg VYEPTI (N=356), or 300 mg VYEPTI (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 (except onabotulinumtoxinA). Patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute medication overuse (triptans, ergotamine, or combination analgesics greater than 10 days per month) were included in the study population. Patients using opioids or butalbital-containing products greater than 4 days per month were not allowed.

The study excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days over Months 1-3. Secondary endpoints included the percentages of patients with 50% or greater and 75% or greater reductions from baseline in monthly migraine days over Months 1-3.

Patients had a median age of 41 years (range: 18 to 65 years), 88% were female, and 91% were white. Forty-one percent of patients were taking concomitant preventive medication for migraine. The mean migraine frequency at baseline was approximately 16.1 migraine days per month and was similar across treatment groups.

VYEPTI treatment demonstrated statistically significant improvements compared to placebo for the primary efficacy endpoint, as shown in Table 3; secondary endpoints are also summarized in Table 3.

Table 3. Efficacy Endpoint Results in Study 2

	VYEPTI 100 mg N=356	VYEPTI 300 mg N=350	Placebo N=366
Monthly Migraine Days (MMD) – Months 1-3			
Change from baseline	-7.7	-8.2	-5.6
Difference from placebo	-2.0	-2.6	
p-value	<0.001	<0.001	
≥50% MMD responders – Months 1-3			
% Responders	57.6%	61.4%	39.3%
Difference from placebo	18.2%	22.1%	
p-value	<0.001	<0.001	
≥75% MMD responders – Months 1-3			
% Responders	26.7%	33.1%	15.0%
Difference from placebo	11.7%	18.1%	
p-value	<0.001	<0.001	

Figure 4 shows the mean change from baseline in average monthly migraine days for Study 2. Patients treated with VYEPTI at both doses had greater mean decreases from baseline in mean monthly migraine days over Month 1-3 compared to placebo-treated patients.

Figure 4. Change from Baseline in Monthly Migraine Days in Study 2

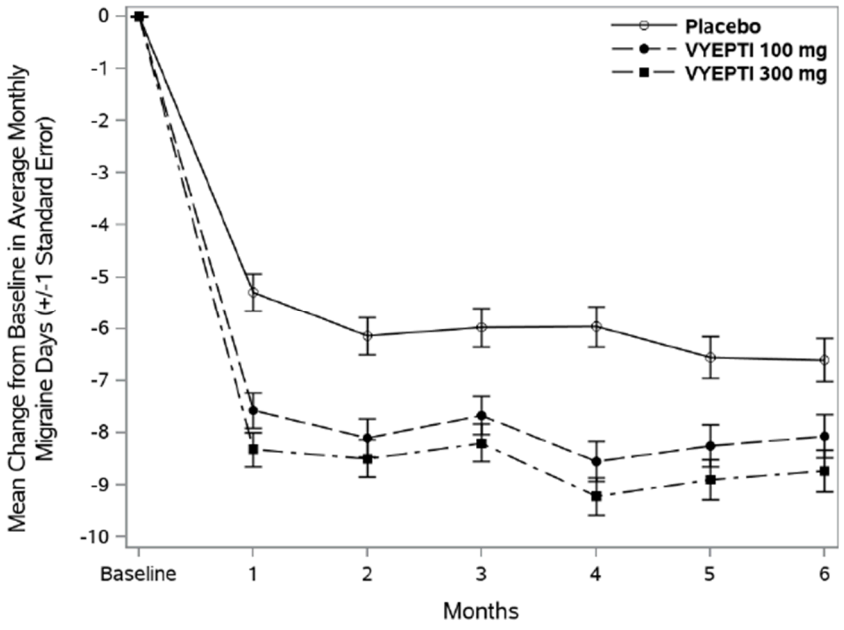


Figure 5 shows the distribution of change from baseline in mean monthly migraine days through Month 3 by treatment group in 3-day increments.

Figure 5. Distribution of Change from Baseline in Mean Monthly Migraine Days over Months 1-3 by Treatment Group in Study 2

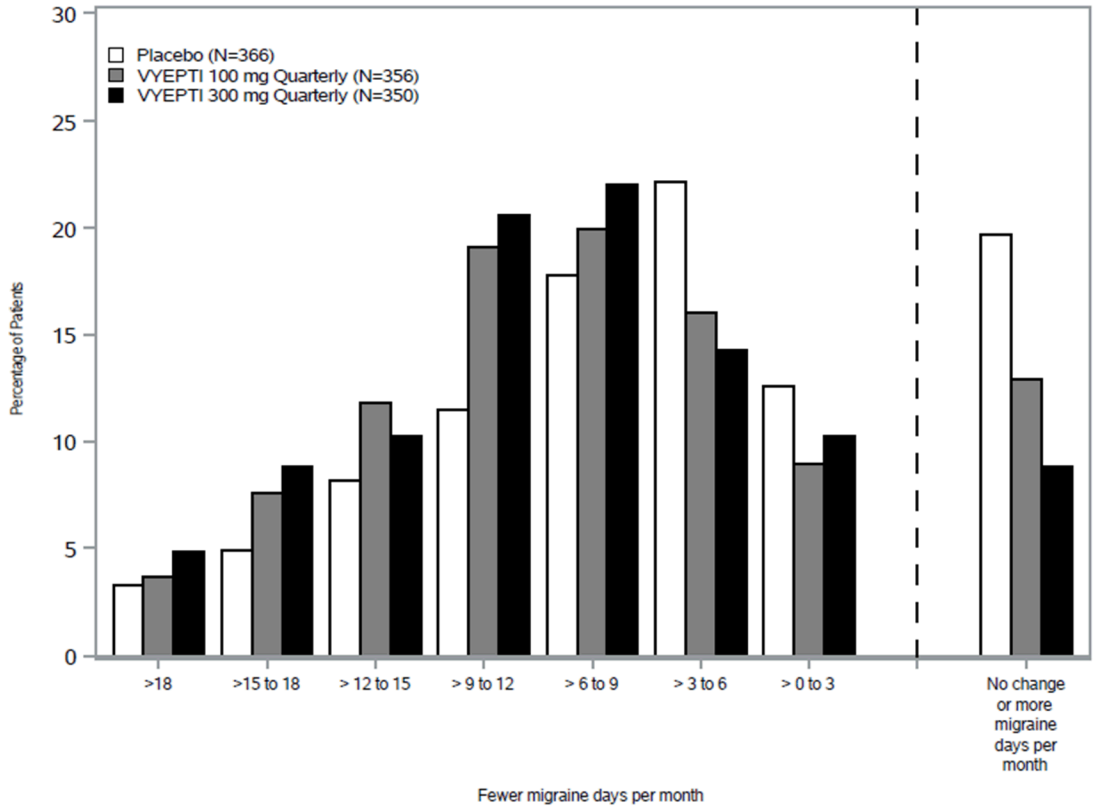
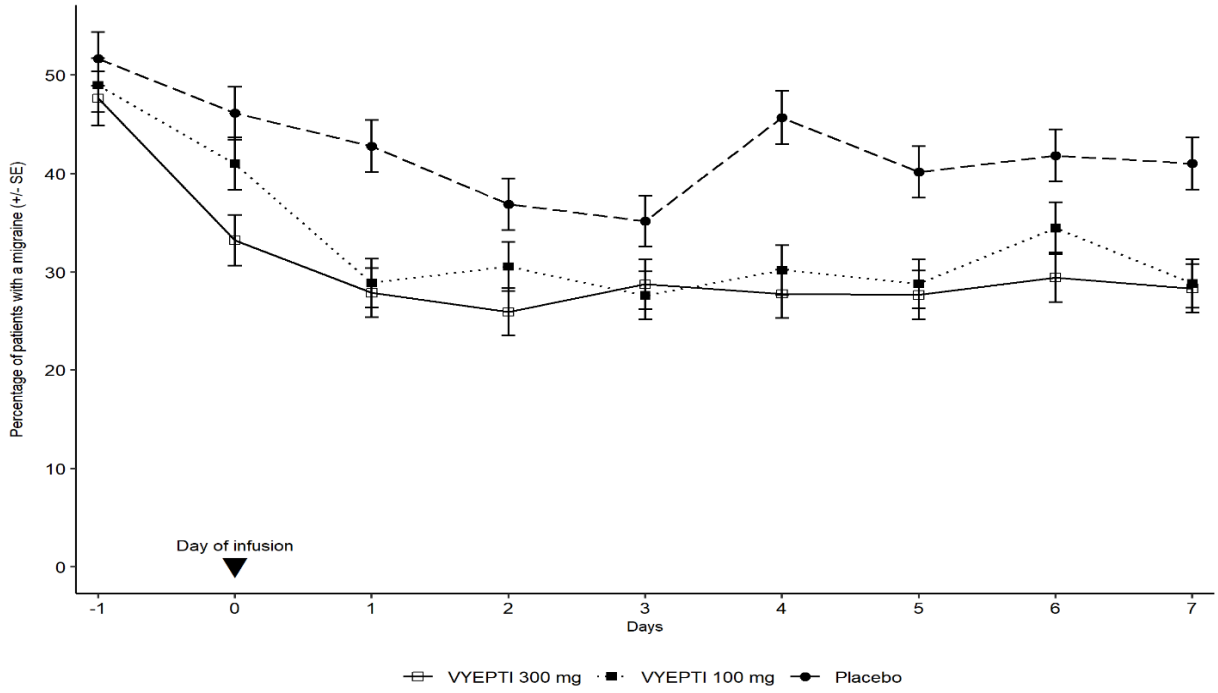


Figure 6 demonstrates that greater percentages of placebo-treated patients had migraines on individual days during the first 7 days of treatment compared to VYEPTI-treated patients in Study 2.

Figure 6. Percentage of Patients with a Migraine from Day -1 (Day Prior to Infusion) to Day 7 in Study 2



Study 3: Episodic Migraine or Chronic Migraine

Study 3 (NCT01719055) included adults who were candidates for preventive migraine therapy with VYEPTI and presented with a concurrent moderate to severe migraine on the day of infusion. A total of 480 patients were randomized to receive 100 mg VYEPTI (n=238) or placebo (n=242) as a single dose. VYEPTI demonstrated statistically significant improvements in headache pain freedom at 2 hours (VYEPTI 23.5% vs placebo 12%; p<0.001) and absence of most bothersome symptom (such as nausea, photophobia, or phonophobia) at 2 hours (VYEPTI 55.5% vs placebo 35.8%; p< 0.001) as compared to placebo. The dose of 300 mg VYEPTI was not evaluated in Study 3.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

VYEPTI (eptinezumab-jjmr) injection is a clear to slightly opalescent, colorless to brownish-yellow solution supplied as:

Carton containing one 100 mg/mL single-dose vial - NDC 67386-130-51.

16.2 Storage and Handling

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze or shake.

The vial stopper is not made with natural rubber latex.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Hypersensitivity Reactions

Inform patients about the signs and symptoms of hypersensitivity reactions and that these reactions can occur with VYEPTI. Advise patients to contact their healthcare provider immediately if signs or symptoms of hypersensitivity reactions occur *[see Warnings and Precautions (5.1)]*.

Constipation with Serious Complications

Inform patients that constipation with serious complications can occur with VYEPTI. Advise patients to contact their healthcare providers if they experience severe constipation *[see Warnings and Precautions (5.2)]*.

Hypertension

Inform patients that hypertension can develop or pre-existing hypertension can worsen with VYEPTI, and that they should contact their healthcare provider if they experience elevation in their blood pressure *[see Warnings and Precautions (5.3)]*.

Raynaud’s Phenomenon

Inform patients that Raynaud’s phenomenon can develop or worsen with VYEPTI. Advise patients to discontinue VYEPTI treatment and contact their healthcare provider if they experience signs or symptoms of Raynaud’s phenomenon *[see Warnings and Precautions (5.4)]*.

Pregnancy Exposure Registry

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYEPTI during pregnancy *[see Use in Specific Populations (8.1)]*.

Lactation

Inform patients to notify their healthcare provider if they are breastfeeding or plan to breastfeed *[see Use in Specific Populations (8.2)]*.

Manufactured by:
Lundbeck Seattle BioPharmaceuticals, Inc.
11804 North Creek Parkway South
Bothell, WA 98011 USA
U.S. License No. 2097

Vyepti is a registered trademark of Lundbeck Seattle BioPharmaceuticals, Inc.

PATIENT INFORMATION
VYEPTI® (vye ep' tee)
(eptinezumab-jjmr)
injection, for intravenous use

What is VYEPTI?
VYEPTI is a prescription medicine used for the preventive treatment of migraine in adults.
It is not known if VYEPTI is safe and effective in children.

Do not receive VYEPTI if you are allergic to eptinezumab-jjmr or any of the ingredients in VYEPTI. See the end of this Patient Information leaflet for a complete list of ingredients in VYEPTI.

Before you receive VYEPTI, tell your healthcare provider about all of your medical conditions, including if you:
- have high blood pressure.
- have circulation problems in your fingers and toes.
- are pregnant or plan to become pregnant. It is not known if VYEPTI will harm your unborn baby.
  - Pregnancy Registry: There is a pregnancy registry for women who take VYEPTI. The purpose of this registry is to collect information about the health of you and your baby. You may enroll yourself by calling 1-855-810-8549 or by visiting www.vyeptipregnancyregistry.lundbeck.com. Or you may talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. It is not known if VYEPTI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using VYEPTI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive VYEPTI?
- VYEPTI will be given by a healthcare provider in a healthcare setting.
- VYEPTI is given by intravenous (IV) infusion in your vein.
- VYEPTI will be given over 30 minutes every 3 months.

If you have questions about your infusion schedule, ask your healthcare provider.

What are the possible side effects of VYEPTI?
VYEPTI may cause serious side effects, including:
- **Allergic reactions.** Allergic reactions can happen after receiving VYEPTI. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - rash
  - swelling of your face, lips, tongue or throat
  - trouble breathing
  - hives
  - redness in your face
- **Constipation with serious complications.** Severe constipation can happen after receiving VYEPTI. In some cases, people have been hospitalized. Contact your healthcare provider if you have severe constipation or constipation is associated with symptoms such as severe or constant belly pain, vomiting, swelling of belly, or bloating.
- **High blood pressure.** High blood pressure or worsening of high blood pressure can happen after receiving VYEPTI. Contact your healthcare provider if you have an increase in blood pressure.
- **Raynaud's phenomenon.** A type of circulation problem can worsen or happen after receiving VYEPTI. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale, to blue, to red. Contact your healthcare provider if these symptoms occur.

The most common side effects of VYEPTI include:
- stuffy nose and scratchy throat
- allergic reactions

These are not all of the possible side effects of VYEPTI.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of VYEPTI.
Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet.
You can ask your pharmacist or healthcare provider for information about VYEPTI that is written for health professionals.

What are the ingredients in VYEPTI?
Active ingredient: eptinezumab-jjmr
Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sorbitol, and Water for Injection.

The vial stopper is not made with natural rubber latex.

Manufactured by: Lundbeck Seattle BioPharmaceuticals, Inc., 11804 North Creek Parkway South, Bothell, WA 98011
US License Number: 2097
Vyepti is a registered trademark of Lundbeck Seattle BioPharmaceuticals, Inc.
For more information, call 1-833-4-VYEPTI (833-489-3784) or go to www.Vyepti.com.
This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 06/2026