Eptinezumab-jjmr tightly binds and stays bound to CGRP, for sustained suppression of the CGRP signaling pathway.

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

CGRP, calcitonin gene-related peptide.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients. Reactions have included anaphylaxis and angioedema.

Please see additional Important Safety Information throughout this document. For more information, please see the accompanying Full Prescribing Information, including Patient Information.
VYEPTI (EPTINEZUMAB-JJMR) IS DESIGNED FOR FAST, POWERFUL, AND SUSTAINED RESPONSE

**RAPID ONSET OF ACTIVITY**

Immediate availability post-infusion

- 100% bioavailability post-intravenous (IV) administration
- Time to maximum concentration: 30 minutes (end of infusion)

**NO OFF-TARGET ACTIVITY**

Selective binding

- High selectivity for CGRP ligand
- Binds to both α- and β-forms of the CGRP ligand

**SUSTAINED DURATION OF ACTION**

Strong binding with minimal disassociation

- High affinity for CGRP ligand
- Terminal half-life of ~27 days

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity reactions:** Hypersensitivity reactions, including angioedema, urticaria, facial flushing, and rash, have occurred with VYEPTI in clinical trials. 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.

Please see additional Important Safety Information throughout this document. For more information, please see the accompanying Full Prescribing Information, including Patient Information.
ALL 6 CDRs OF EPTINEZUMAB-JJMR INTERACT WITH AND ARE IN CONTACT WITH CGRP¹

This is consistent with the properties of specificity, durability and strength of binding

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

Eptinezumab-jjmr features were designed for rapid onset and sustained duration of action²⁻³

Cmax, maximum observed concentration; CGRP, calcitonin gene-related peptide; CDRs, complementarity-determining regions; Kd, disassociation constant.

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS

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

Please see additional Important Safety Information throughout this document.
For more information, please see the accompanying Full Prescribing Information, including Patient Information.
JUST ONE 30-MINUTE IV TREATMENT EVERY 3 MONTHS

- Recommended dosing: 100 mg administered by IV infusion every 3 months
- Some patients may benefit from 300 mg administered by IV infusion every 3 months

Saturable inhibitory maximum-effect (E\text{max}) model conclusions

Exposure over 12 weeks produced by single-dose eptinezumab-jjmr 100 and 300 mg exceeded the exposure estimates required to achieve 90% of the maximal efficacy (EC\text{90}).

- Supports dosing every 12 weeks with no adjustment for patient characteristics.
- Supports 100 mg as the lowest effective dose of eptinezumab-jjmr.

To learn more about VYEPTI, visit vyeptihcp.com

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

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

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

Please see additional Important Safety Information throughout this document. For more information, please see the accompanying Full Prescribing Information, including Patient Information.

VYEPTI® (optineuzumab-jjmr) injection, for intravenous use

**INDICATIONS AND USAGE**

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

**CONTRAINDICATIONS**

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients in VYEPTI.

**WARNINGS AND PRECAUTIONS**

- Hypersensitivity Reactions: If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and initiate appropriate therapy.

**ADVERSE REACTIONS**

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

- Hypersensitivity Reactions

**DOSE AND ADMINISTRATION**

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 every 3 months.

2. **Dilution Instructions**

   - VYEPTI requires dilution prior to administration. Dilute only in 100 mL of 0.9% Sodium Chloride Injection, USP. 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, USP.

   - **Dilution 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, USP.

- **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.

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 is cloudy or discolored.

   - 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, USP.

**DOSE FORMS AND STRENGTHS**

VYEPTI is a clear to slightly opalescent, colorless to brownish-yellow solution available as 3 dosage forms and strengths with a 0.2 micron or 0.22 micron in-line or add-on sterile filter. After the infusion is complete, VYEPTI is for intravenous infusion only; infuse over approximately 30 minutes. Do not use if the liquid prior to administration, whenever solution and container permit. Do not mix with any other medications.

**Contraindications**

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients.

**Warnings and Precautions**

Hypersensitivity Reactions: If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and initiate appropriate therapy.

**Adverse Reactions**

The most common adverse reactions (≥2% and 2% or greater than placebo) were nasopharyngitis and hypersensitivity.

**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**

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>VYEPTI 100 mg</th>
<th>VYEPTI 300 mg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>6</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Hypersensitivity reactions</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

*Hypersensitivity reactions include multiple related adverse events 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)].

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to eptinezumab-jjmr in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

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% (39/92) 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.

6.3 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.

Immune System Disorders - Anaphylaxis [see Contraindications (4) and Warnings and Precautions (5.1)].

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

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 pre-eclampsia 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 kDa. 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 (2.5 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.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

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

Mutagenesis

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

Impairment of Fertility

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly in 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 as a preventive treatment of episodic and chronic migraine in two randomized, multicenter, placebo-controlled studies, both with 6-month double-blind periods: one study in patients with episodic migraine (Study 1) and one study in patients with chronic migraine (Study 2). VYEPTI was administered by intravenous infusion every 3 months in both studies; however, the primary endpoint was measured at 12 weeks.

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

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

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

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.

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

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

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

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
Advising 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)].

Pregnancy
Advising patients to notify their healthcare provider if they become pregnant during treatment or plan to become pregnant [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
US License No. 2097

Vyepti is a registered trademark of Lundbeck Seattle BioPharmaceuticals, Inc. EPT-L-100009

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:
• are pregnant or plan to become pregnant. It is not known if VYEPTI will harm your unborn baby.
• are breastfeeding or plan to breastfeeding. 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
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: 09/2021