

## Package leaflet: Information for the patient

### VYEPTI 100 mg concentrate for solution for infusion VYEPTI 300 mg concentrate for solution for infusion eptinezumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What VYEPTI is and what it is used for
2. What you need to know before you are given VYEPTI
3. How to use VYEPTI
4. Possible side effects
5. How to store VYEPTI
6. Contents of the pack and other information

#### **1. What VYEPTI is and what it is used for**

VYEPTI contains the active substance eptinezumab, which blocks the activity of calcitonin gene-related peptide (CGRP), a naturally occurring substance in the body. People with migraine may have increased levels of this substance.

VYEPTI is used to **prevent migraine** in adults who have migraine at least 4 days per month.

VYEPTI can reduce the number of days with migraine and improve your quality of life. You may feel the preventive effect starting the day after receiving this medicine.

#### **2. What you need to know before you are given VYEPTI**

##### **Do not use VYEPTI**

- if you are allergic to eptinezumab or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or nurse before being given VYEPTI if you have disease affecting the heart and blood circulation.

VYEPTI can cause serious allergic reactions. These reactions can develop quickly even while the medicine is being given. Tell your doctor immediately if you get any symptoms of an allergic reaction, such as:

- breathing difficulty
- a fast or weak pulse or a sudden drop in blood pressure which makes you feel dizzy or lightheaded

- swelling of the lips or tongue
- severe itching of the skin or rash while you receive VYEPTI, or afterwards

### **Children and adolescents**

VYEPTI is not recommended for children or adolescents under 18 years because it has not been studied in this age group.

### **Other medicines and VYEPTI**

Tell your doctor if you are using, have recently used or might use any other medicines.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

It is preferable to avoid the use of VYEPTI during pregnancy as the effects of this medicine in pregnant women are not known.

It is not known if VYEPTI passes into breast milk. Your doctor will help you decide if you should stop breast-feeding or stop VYEPTI treatment. If you are breast-feeding or are planning to breast-feed, talk to your doctor before being treated with VYEPTI. You and your doctor should decide if you should breast-feed and be treated with VYEPTI.

### **Driving and using machines**

VYEPTI has no or negligible effect on the ability to drive or use machines.

### **VYEPTI contains sorbitol**

Sorbitol is a source of fructose. If you have hereditary fructose intolerance (HFI), a rare genetic disorder, you must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you have HFI.

## **3. How to use VYEPTI**

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

VYEPTI is given as a drip (infusion) into a vein. The infusion lasts about 30 minutes. VYEPTI will be given to you by a healthcare professional, who prepares the infusion before giving it to you. During and after the infusion the healthcare professional will observe you in accordance with normal clinical practice for signs of an allergic reaction.

The recommended dose is 100 mg given every 12 weeks. Some patients may benefit from a dose of 300 mg given every 12 weeks. Your doctor will decide the right dose for you and how long you should continue to be treated.

### **If you use more VYEPTI than you should**

Because the medicine will be given to you by a healthcare professional, it is unlikely you will receive too much VYEPTI. Inform your doctor if you think this has happened.

### **If you forget to use VYEPTI**

If a dose is missed, your doctor will decide when the next dose should be given.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor or nurse immediately** if you notice any of the following side effects – you may need urgent medical treatment:

**Common:** may affect up to 1 in 10 people:

- **allergic reactions and other reactions due to the infusion**

Reactions can develop quickly during infusion. Symptoms of allergic reactions are:

- breathing difficulties
- fast or weak pulse
- sudden drop in blood pressure making you feel dizzy or lightheaded
- swelling of the lips or tongue
- severe skin itching, rash

Serious allergic reactions are uncommon (may affect up to 1 in 100 people).

Other symptoms that may occur due to the infusion include respiratory symptoms (such as blocked or runny nose, throat irritation, cough, sneezing, shortness of breath) and feeling tired. These symptoms are usually non-serious and of short duration.

Other side effects can occur with following frequency:

Common: may affect up to 1 in 10 people:

- stuffy nose
- sore throat
- fatigue

#### Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

##### United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store VYEPTI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze or shake.

Keep the vial in the outer carton in order to protect from light.

If removed from the refrigerator, VYEPTI must be kept at room temperature (below 25°C) in the original carton and used within 2 days, or else discarded. Do not put VYEPTI back in the refrigerator once it has been removed.

After dilution, the solution may be stored at room temperature (below 25°C) or in a refrigerator at 2°C - 8°C. The diluted solution for infusion must be given within 8 hours.

Do not use this medicine if you notice that the solution contains visible particles or is cloudy or discoloured.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What VYEPTI contains**

- The active substance is eptinezumab.
- Each vial of 100 mg concentrate contains 100 mg of eptinezumab per mL.
- Each vial of 300 mg concentrate contains 300 mg of eptinezumab per 3 mL.
- The other ingredients are sorbitol (E420), L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80 and water for injections.

### **What VYEPTI looks like and contents of the pack**

VYEPTI concentrate for solution for infusion is clear to slightly milky, colourless to brownish-yellow. Each vial contains concentrate in a clear glass vial with a rubber stopper, aluminium seal and plastic flip-off cap.

VYEPTI 100 mg concentrate is available in pack size of 1 vial for single-use.

VYEPTI 300 mg concentrate is available in pack size of 1 vial for single-use.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Lundbeck Limited  
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United Kingdom

### **Manufacturer**

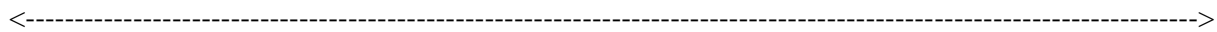
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

### **United Kingdom**

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**This leaflet was last revised in 12/2023.**



The following information is intended for healthcare professionals only:

#### Instructions for dilution and administration

The medicinal product requires dilution prior to administration. The dilution should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared solution for infusion.

The medicinal product contains no preservative and is intended for single use only and any unused medicinal product should be disposed.

Prior to dilution, the medicinal product (concentrate in the vials) should be inspected visually; do not use if the concentrate contains visible particulate matter or is cloudy or discoloured (other than clear to slightly opalescent, colourless to brownish-yellow).

For both the 100 mg and the 300 mg dose, a 100 mL bag of sodium chloride 9 mg/mL (0.9%) solution for injection should be used to prepare the VYEPTI solution for infusion as described below. No other intravenous diluents or volume may be used to prepare the VYEPTI solution for infusion.

Gently invert the VYEPTI solution for infusion to mix completely. Do not shake.

Following dilution, VYEPTI solution for infusion must be infused within 8 hours. During this time, VYEPTI solution for infusion may be stored at room temperature (below 25°C) or refrigerated at 2°C - 8°C. If stored at 2°C - 8°C, allow the VYEPTI solution for infusion to warm to room temperature prior to infusion. **DO NOT FREEZE.**

- VYEPTI 100 mg dose

To prepare the VYEPTI solution for infusion, withdraw 1.0 mL of VYEPTI from one single-use 100 mg vial using a sterile needle and syringe. Inject the 1.0 mL (100 mg) content into a 100 mL bag of 0.9% sodium chloride for injection

- VYEPTI 300 mg dose

To prepare the VYEPTI solution for infusion, withdraw 1.0 mL of VYEPTI from 3 single-use 100 mg vials or 3.0 mL of VYEPTI from one single-use 300 mg vial using a sterile needle and syringe. Inject the resulting 3.0 mL (300 mg) content into a 100 mL bag of 0.9% sodium chloride for injection.

#### **Infusion administration instructions**

Parenteral medicinal 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.

Infuse VYEPTI 100 mg dose or VYEPTI 300 mg dose as prescribed, following dilution of the vial content in a 100 mL bag of 0.9% sodium chloride for injection, over approximately 30 minutes. Use an intravenous infusion set with a 0.2 or 0.22 µm in-line or add-on filter. After the infusion is complete, flush the line with 20 mL of 0.9% sodium chloride for injection.

Do not administer VYEPTI as a bolus injection.

No other medications should be administered through the infusion set or mixed with VYEPTI.

Any unused medicinal product or waste material should be disposed in accordance with local requirements.