

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**VYEPTI**®

(Eptinezumab for injection, solution for intravenous infusion)

Read this carefully before you start taking **Vyepti** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Vyepti**.

What is Vyepti used for?

- Vyepti is a medicine used to prevent migraine in adults who have at least 4 migraine days per month.

How does Vyepti work?

Vyepti contains the active ingredient eptinezumab, which belongs to a group of substances called monoclonal antibodies. Eptinezumab blocks the activity of a protein called calcitonin gene-related peptide (CGRP). Increases in CGRP levels in the blood have been linked to migraine.

What are the ingredients in Vyepti?

Medicinal ingredient: eptinezumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride, polysorbate 80, sorbitol and water for injection.

Vyepti comes in the following dosage forms:

- 1 mL solution containing 100 mg of eptinezumab (100 mg/mL) per single-use vial for intravenous infusion.
- 3 mL solution containing 300 mg of eptinezumab (300 mg/3 mL) per single-use vial for intravenous infusion.

Do not use Vyepti if:

- you are allergic to eptinezumab or any of the other ingredients of this medicine (see What are the ingredients in Vyepti? above)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Vyepti. Talk about any health conditions or problems you may have, including:

- heart disease
- severe liver disease
- severe kidney disease
- alcohol/drug abuse
- severe mental disorders
- intolerance to sorbitol

Vyepti can potentially cause serious allergic reactions. These reactions can develop quickly during the infusion.

Talk to your doctor or nurse immediately if you get any symptoms of an allergic reaction such as difficulty breathing, a fast or weak pulse or a sudden drop in blood pressure (making you feel dizzy or lightheaded), swelling of the lips or tongue, severe itching or rash while you receive Vyepti or afterwards.

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.

Other warnings you should know about:**Children and adolescents**

Vyepti should not be given to children under 18 years old. The use of Vyepti has **not** been studied in children.

Pregnancy and breast-feeding

Vyepti has **not** been studied in pregnant women.

Ask your doctor for advice before receiving this medicine, if you:

- are pregnant or think you may be pregnant
- are planning to have a baby
- are breast-feeding or planning to breastfeed

Your doctor will help you decide if Vyepti is right for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Vyepti :

Vyepti will be given to you by a healthcare professional in a healthcare setting.

- Vyepti is given by an intravenous infusion (through a needle placed in a vein in the arm, hand, or through a central line). The infusion lasts about 30 minutes.

Usual dose:

The recommended dose is 100 mg Vyepti every 12 weeks. Some patients may benefit from a dosage of 300 mg every 12 weeks.

Before starting the treatment, your doctor will determine the amount of Vyepti required.

Overdose:

If you think you, or a person you are caring for, have taken too much Vyepti, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, contact your healthcare professional immediately for instructions.

What are possible side effects from using Vyepti?

These are not all the possible side effects you may have when taking Vyepti. If you experience any side effects not listed here, tell your healthcare professional.

Common (≥ 1 in 100 and < 1 in 10)

- Nasopharyngitis (stuffy nose and sore throat)
- Allergic reaction (rash, swelling, itching, hives, itchy throat or tightness, difficulty breathing and wheezing)

- Reactions due to the infusion (feeling tired, respiratory symptoms such as blocked or runny nose, throat irritation, cough, sneezing, shortness of breath).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
UNCOMMON (≥ 1 in 1,000 and < 1 in 100)			
Serious allergic reactions: difficulty breathing, fast or weak pulse or sudden drop in blood pressure (making you feel dizzy or lightheaded), swelling of the lips or tongue, severe itching of the skin, or rash.		X	X

Other side effects can include infusion site reactions such as redness, swelling, or pain.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Vyepti shall be:

- Stored in original package to protect from light.
- Stored in a refrigerator (2°C – 8°C).

If removed from the refrigerator, Vyepti must be used within 7 days when stored in original carton at room temperature (up to 25°C) or discarded. If it is stored at a higher temperature or for a longer period it must be discarded.

Do **not** freeze or shake.

Keep out of reach and sight of children.

If you want more information about Vyepti:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health->

canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.lundbeck.com/ca/en, or by calling 1-800-586-2325.

This leaflet was prepared by Lundbeck Canada Inc., Saint-Laurent, QC, H4S 0A9

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