VYEPTI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VYEPTI®?

VYEPTI® contains the active ingredient eptinezumab. VYEPTI® is used for the preventive treatment of migraine in adults.

For more information, see Section 1. Why am I using VYEPTI®? in the full CMI.

2. What should I know before I use VYEPTI®?

Do not use if you have ever had an allergic reaction to eptinezumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use VYEPTI®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VYEPTI® and affect how it works.

See Section 3. What if I am taking other medicines? in the full CMI.

4. How do I receive VYEPTI®?

VYEPTI® is given to you in the hospital or clinic. VYEPTI® should be administered under the guidance and supervision of a doctor or healthcare professional. The recommended dosage is 100 mg administered by intravenous infusion.

VYEPTI® should be administered once every 3 months (12 weeks).

More instructions can be found in Section 4. How do I use VYEPTI®? in the full CMI.

5. What should I know while using VYEPTI®?

Things you should do	Remind any doctor or dentist you visit that you are using VYEPTI®. If you become pregnant while being given this medicine, tell your doctor immediately.
Things you should not do	This medicine is prescribed to you by your doctor. Do not stop your VYEPTI® treatment without talking to your doctor first.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how VYEPTI® affects you. This medicine is not expected to affect your ability to drive a car or operate machinery.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	It should be stored in a refrigerator (2°C to 8°C). Do not freeze or shake.

For more information, see Section 5. What should I know while using VYEPTI®? in the full CMI.

6. Are there any side effects?

Some of the less serious side effects include: Allergic reactions (e.g. hives, rash, itching and flushing/hot flush), high blood pressure, infection of the nose and throat, feeling tired and constipation.

Some of the serious side effects include: Serious allergic reactions, which may have symptoms of difficulty breathing, a fast or weak pulse or a sudden drop in blood pressure (making you feel dizzy or lightheaded), swelling of the face, lips, tongue or other parts of the body.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

VYEPTI® (vye ep' tee)

Active ingredient(s): *EPTINEZUMAB*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VYEPTI®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VYEPTI®.**

Where to find information in this leaflet:

1. Why am I using VYEPTI®?
2. What should I know before I use VYEPTI®?
3. What if I am taking other medicines?
4. How do I receive VYEPTI®?
5. What should I know while using VYEPTI®?
6. Are there any side effects?
7. Product details

1. Why am I using VYEPTI®?

VYEPTI® contains the active ingredient eptinezumab. VYEPTI® belongs to a group of medicines which are comprised of antibodies that inhibit the activity of calcitonin-gene-related peptide (CGRP). VYPETI® works by blocking the activity of CGRP. Increased levels of CGRP are associated with migraines.

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

2. What should I know before I use VYEPTI®?

Warnings

Do not use VYEPTI® if:

1. You are allergic to eptinezumab, or any of the ingredients listed at the end of this leaflet.
2. Always check the ingredients to make sure you can use this medicine.
3. Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- a fast or weak pulse or a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.
- redness in your face

Check with your doctor if you:

- have any other medical conditions including
    - cardiovascular disease (e.g. hypertension or ischemic heart disease). VYEPTI® has not been studied in patients with a history of cardiovascular disease, there is limited safety information on these patients.
    - Constipation has been reported in some people taking VYEPTI®. In most cases, it was mild and resolved on its own. In rare cases, constipation may be serious, particularly in people with a history of constipation, certain medical conditions, or who take medicines that may slow bowel movements. Tell your doctor if you experience severe constipation, or constipation with ongoing stomach pain, vomiting, abdominal swelling, or severe bloating.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is a very limited amount of information regarding the use of VYEPTI® in pregnant women. Your doctor will discuss with you the benefits of using VYEPTI® against the potential the risk to the foetus.

It is not known if VYEPTI® is passed into breast milk, nor what the potential effects on the breast-fed infant may be. Your doctor will help you decide if you should stop breast-feeding or stop using VYEPTI®. Talk to your doctor about the best way to feed your baby while using Vyepti®.

Use in children

- VYEPTI® has not been studied in patients under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VYEPTI® and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYEPTI®.

4. How do I receive VYEPTI®?

How much is given to you

- VYEPTI® is given to you in the hospital or clinic.
- VYEPTI® should be administered under the guidance and supervision of a doctor or healthcare professional.

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

When VYEPTI® is given

- VYEPTI® should be administered every 12 weeks in a hospital or clinical setting.

How VYEPTI® is given

- VYEPTI® will be given by a healthcare professional in a healthcare setting
- VYEPTI® is given by intravenous infusion in your vein
- VYEPTI® should be administered once every 3 months (12 weeks)
- Once prepared, VYEPTI® is administered by intravenous infusion over approximately 30 minutes.

Ask your doctor or healthcare professional if you have questions about your infusion schedule.

If you miss a dose of VYEPTI®

VYEPTI® is given every 3 months, under the supervision of a doctor or healthcare professional. If you miss or forget your appointment for VYEPTI®, contact your doctor and make another appointment as soon as possible. Do not wait for the next scheduled dose.

If you use too much VYEPTI®

As this medicine is being given by your doctor or healthcare professional in a hospital or clinical setting, it is unlikely that you will be given the wrong dose. In the unlikely event of an overdose, your doctor will monitor you for side effects and treat any of your symptoms as required.

5. What should I know while using VYEPTI®?

Things you should do

If you become pregnant while being given this medicine, tell your doctor immediately.

Tell your doctor or healthcare professional straight away if you:

- feel unwell during infusion. Typical symptoms associated with allergic reactions are redness of the face or chest, itching, coughing, shortness of breath, chest discomfort, etc. Serious allergic reactions may have symptoms of difficulty breathing, a fast or weak pulse or a sudden drop in blood pressure (making you feel dizzy or lightheaded), swelling of the face, lips, tongue or other parts of the body.
    - o These side effects mostly occur during infusion. Steps should be taken by healthcare professionals to monitor any changes to your condition during the treatment with VYEPTI®.
    - o Depending on the seriousness of the side effect, the infusion may be discontinued, and appropriate treatment for the side effect may be given.

Remind any doctor or dentist you visit that you are using VYEPTI®.

Things you should not do

- This medicine is prescribed to you by your doctor. Do not stop your VYEPTI® treatment without talking to your doctor first.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VYEPTI® affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- It should be stored in a refrigerator (2°C to 8°C).
- Do not freeze or shake.
- It should be stored in original packaging in order to protect it from light.
- If removed from the refrigerator, VYEPTI® must be kept at room temperature (≤25°C) in the original carton and used within 7 days. VYEPTI® must not be returned to the refrigerator.
- If VYEPTI® is allowed to remain out of the refrigerator at ≤25°C for more than 7 days, it must not be used and should be returned to the pharmacy for destruction.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine

VYEPTI® is for single use in one patient only. Any residue must be discarded.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Allergy related: • Allergic reactions (e.g. hives, rash, itching and flushing/hot flush)	**Speak to your doctor if you have any of these less**

Less serious side effects	What to do
Blood vessel-related: • High blood pressure or worsening of high blood pressure. **Related to receiving VYEPTI:** • Nasal congestion, runny nose, sore throat, cough, sneezing, difficulty breathing • Feeling tired. • Constipation **Infection-related:** • Infection of the nose and throat.	**serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Some of the symptoms of a serious allergic reaction may include: • Difficulty breathing, a fast or weak pulse or a sudden drop in blood pressure (making you feel dizzy or lightheaded), swelling of the face, lips, tongue or other parts of the body.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VYEPTI® contains

Active ingredient (main ingredient)	• Eptinezumab VYEPTI® 100 mg/mL contains 100 mg of eptinezumab in 1.0 mL
Other ingredients	• Histidine
(inactive ingredients)	• Histidine hydrochloride monohydrate • Polysorbate 80 • Sorbitol • Water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

The vial stopper is not made with natural rubber latex.

What VYEPTI® looks like

VYEPTI® is a concentrated injection for dilution for infusion.

Each carton contains one vial.

Aust R 335256

Who distributes VYEPTI®

Lundbeck Australia Pty Ltd

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Ph: 02 8669 1000

This leaflet was prepared in July 2026.