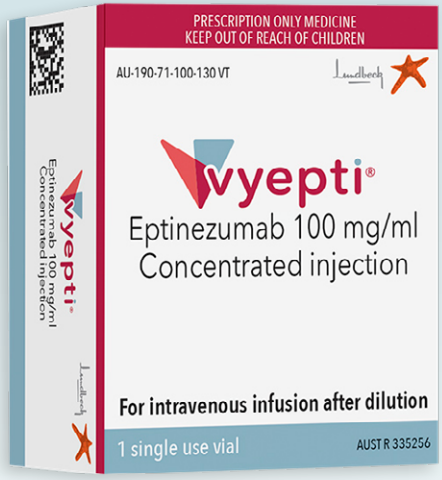
vyepti®
(eptinezumab)
100 mg/mL

How to administer Vyepti® (eptinezumab)



The first intravenous anti-CGRP monoclonal antibody treatment available in Australia[1]

30 min IV infusion[1]

Four times a year[1]

100 mg dose recommended[1]

Storing and diluting Vyepti®[1]

Storing Vyepti[1]

Information on the shelf life of Vyepti can be found in the public summary of the Australian Register of Therapeutic Goods (ARTG).
The expiry date can be found on the packaging.

Before diluting

Keep vials refrigerated at 2–8°C in original carton to protect from light until time of use

Refrigerated vials do not need to equilibrate to room temperature before dilution

If removed from the refrigerator, VYEPTI® must be kept at room temperature (≤25°C) in the original carton and used within 2 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 2 days, it must not be used and should be returned to the pharmacy for destruction.

Do not freeze

Do not shake

After diluting

Vyepti solution for infusion may be stored at room temperature or refrigerated at 2–8°C for up to 8 hours

Before diluting Vyepti[1]

Vyepti requires dilution prior to administration

Use appropriate aseptic technique when preparing Vyepti solution for intravenous infusion.

Visually inspect the vial before diluting

Vyepti is a clear to slightly opalescent, colourless to brownish-yellow solution. Do not administer Vyepti if the vial or dilution contains visible particulate matter or is cloudy or discoloured.

Diluting Vyepti®[1]

Recommended 100 mg dose

Withdraw 1 mL of Vyepti from **one** single-dose vial* using a sterile needle and syringe

Inject 1 mL Vyepti into a 100 mL bag of 0.9% sodium chloride injection

Do not use any other diluent

300 mg dose

Withdraw 1 mL of Vyepti from each of **three** single-dose vials using a sterile needle and syringe

Inject the 3 mL Vyepti into a 100 mL bag of 0.9% sodium chloride injection

Do not use any other diluent

* Refrigerated vials do not need to equilibrate to room temperature prior to use.

Gently invert the bag to mix completely

✕ Do not shake

Vyepti must be infused within 8 hours of dilution

The diluted solution can be kept at room temperature or refrigerated at 2–8°C – do not freeze

Before infusion, allow refrigerated diluted solutions to come to room temperature

Three steps to administering Vyepti®[1]

1

Intravenously administer the diluted Vyepti solution

Use an IV infusion set with a 0.2 or 0.22 µm in-line or add-on sterile filter

2

Infuse over approximately 30 minutes

3

After administration is complete, flush the line with an additional 20 mL of 0.9% sodium chloride solution

Do not remove saline from the 100 mL bag

Do not administer Vyepti as an IV bolus injection

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

Post infusion[1]

Healthcare providers should observe or monitor patients during and after the infusion in accordance with normal clinical practice.

Vyepti® is indicated for the preventive treatment of migraine in adults[1]

Vyepti is contraindicated in individuals with hypersensitivity to eptinezumab or any excipients.[1]

Vyepti recommended dosing[1]

- Vyepti 100 mg is delivered by intravenous infusion over approximately 30 minutes every 12 weeks
- Some individuals may benefit from a 300 mg dose

- Vyepti is supplied as a single-use vial containing 100 mg/mL eptinezumab

Pharmacokinetics[1]

100%

100% bioavailability

Median time to maximum concentration (C_{max})

27 days

Average terminal elimination half-life ($t_{½}$)

SCAN TO LEARN MORE

PBS Information: Authority Required (STREAMLINED), codes: 14189 and 12029. Criteria apply, see www.pbs.gov.au for details.

Vyepti® is indicated for the preventive treatment of migraine in adults.[1]

Please review the full Approved Product Information for Vyepti before prescribing, available by calling Lundbeck on 1300 721 277.

▼ **Black triangle scheme:** This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at https://www.tga.gov.au/reporting-problems.

Minimum Product Information: Vyepti® (eptinezumab). **Indications:** Vyepti is indicated for the preventive treatment of migraine in adults. **Contraindications:** Hypersensitivity to eptinezumab or any of the excipients. **Precautions:** Serious hypersensitivity reactions, including anaphylactic reactions may occur within minutes of the infusion. **Adverse Effects:** The common adverse events are nasopharyngitis, hypersensitivity and *infusion-related reactions**. Most hypersensitivity reactions occurred during the infusion and were not serious; angioedema, urticaria, facial flushing and rash have been reported. Infusion-site related reactions occurred infrequently. **Dosage & Administration:** The recommended dose is 100 mg administered by intravenous infusion every 12 weeks and initiated and supervised by a healthcare professional. Vyepti 100 mg/mL is available as a single-dose vial. Treatment benefit should be assessed 3–6 months after initiation of treatment. Administration: Vyepti is for intravenous infusion only after dilution. Infusion takes place over approximately 30 minutes. For preparation and infusion instructions consult Approved PI. No dosage adjustments are recommended for age, gender or race. No dedicated hepatic and renal impairment studies were conducted; however, population pharmacokinetic analysis revealed no differences that would require dose adjustments. Insufficient data are available for use in elderly, children or adolescents. **Date of TGA approval:** 09 June 2021; **Date of TGA update:** 27 June 2022; **Date of Minimum PI:** 11 July 2022

*Please note changes to minimum product information in italics

Reference: 1. Vyepti® Approved Australian Product information.

vyepti (eptinezumab) 100 mg/mL

Lundbeck