



STEP-BY-STEP INSTRUCTIONS FOR ADMINISTERING VYEPTI®▼ (eptinezumab)

VYEPTI (eptinezumab) is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month¹

Prescribing information can be found [here](#).

VYEPTI is for intravenous use after dilution.
Please refer to the Summary of Product Characteristics (SmPC) for full information.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Lundbeck Limited, 01908 638972 or Email: SafetyLuUnitedKingdom@lundbeck.com



What you need to get started^{1*}

Supplies required per infusion

A VYEPTI 100 mg vial



The concentrate for solution for infusion is clear to slightly opalescent, colourless to brownish-yellow with a pH of 5.5–6.1 and osmolality of 290–350 mOsm/kg.

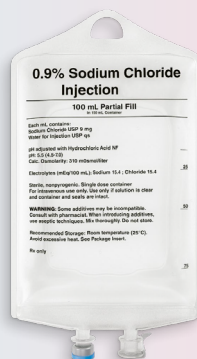
Use an intravenous infusion set with a 0.2 or 0.22 μm in-line or add-on filter



Sterile needle and syringe



100 mL bag of 0.9% Sodium Chloride for Injection



Additional 20 mL of 0.9% Sodium Chloride for Injection



After the infusion is complete, flush the line with 20 mL of 0.9% Sodium Chloride for Injection. This should not be drawn from the 100 mL saline bag.

No other intravenous diluents or volume may be used to prepare the VYEPTI solution for infusion.

Note: For illustrative purposes only; actual materials may vary depending on manufacturer.

* These step-by-step instructions do not include all required materials.

Only VYEPTI 100 mg vials are included with VYEPTI orders. All other infusion materials must be supplied separately.

Dosing and Administration

Pre-infusion¹

Required dilution instructions

VYEPTI requires dilution prior to administration. Use appropriate aseptic technique when preparing VYEPTI solution for intravenous (IV) infusion.

The dilution should be prepared by a Healthcare Professional and treatment should be initiated by a healthcare professional experienced in the diagnosis and treatment of migraine.

Storage and Inspection



- VYEPTI solution should be 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 and keep the vial in the outer carton in order to protect from light.
- 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).
- Make sure the vial and the dilution are inspected prior to dilution or administration respectively.

Dilution



- 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).

- 1 **VYEPTI 100 mg dose:** 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 for Injection. No other diluents may be used.
- 2 Gently invert the VYEPTI solution to mix completely. Do not shake.

Discard Information



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

Infusion¹

- Following dilution, VYEPTI solution must be infused within 8 hours. During this time, VYEPTI solution should 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.
- The infusion of VYEPTI should be initiated and supervised by a healthcare professional.
- 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 discoloured.

3 STEPS TO ADMINISTERING VYEPTI



1 INFUSE

Use an IV infusion set with a 0.2 or 0.22 µm in-line or add-on filter. Do not administer VYEPTI as a bolus injection.



2 OBSERVE

Infuse over approximately 30 minutes.



3 FLUSH

After administration is complete, flush the line with 20 mL of 0.9% Sodium Chloride for Injection (this should not be drawn from the 100 mL saline bag).

The treating healthcare professional should observe or monitor patients during and after the infusion in accordance with normal clinical practice.

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

Post-infusion¹

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



Schedule patient's follow-up or next infusion appointment for 12 weeks time (if applicable).

Please consult the Summary of Product Characteristics (SmPC) for full information.

Frequently Asked Questions

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What were the common adverse events seen in the clinical trials?

The most common adverse events were hypersensitivity reactions, infusion-related reaction and fatigue.¹ These are not all of the possible side effects of VYEPTI.¹ Please consult the full Summary of Product Characteristics (SmPC) in relation to other adverse events.¹

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What should I do if the patient experiences an adverse event during a VYEPTI infusion?

Serious hypersensitivity reactions, including anaphylactic reactions, have been reported and may develop within minutes of the infusion.

If a serious hypersensitivity reaction occurs, administration of VYEPTI should be discontinued immediately and appropriate therapy initiated. If the hypersensitivity reaction is not serious, continuation of further treatment with VYEPTI is up to the discretion of the treating physician, taking into account the benefit-risk for the individual patient.¹

The reported anaphylactic reactions have included symptoms of hypotension and respiratory difficulties, and have led to discontinuation of VYEPTI. Other hypersensitivity reactions, including angioedema, urticaria, flushing, rash and pruritus, were reported in approximately 4% of patients on 300 mg, 3% of patients on 100 mg and 2% of patients on placebo (saline) in clinical studies.

Please note: VYEPTI 300 mg is not available in the UK.

Other symptoms reported in association with eptinezumab infusion include respiratory symptoms (nasal congestion, rhinorrhea, throat irritation, cough, sneezing, dyspnea) and fatigue. Most of these events were non-serious and transient in nature.¹

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product.¹

Adverse event reporting information can be found at the beginning of this material.

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How long should a patient be monitored after receiving a VYEPTI infusion?

The treating healthcare professional should observe or monitor patients during and after the infusion in accordance with normal clinical practice.¹

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Are there any pre-infusion or post-infusion medications required or recommended?

No, there are no required or recommended pre-infusion or post-infusion medications for patients receiving VYEPTI. **No other medications should be administered through the infusion set or mixed with VYEPTI.¹**