Prescribing Information

VYEPTI®▼(eptinezumab) 100 mg concentrate for solution for infusion

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing, particularly in relation to side effects, precautions and contraindications.

Presentation: Eptinezumab 100 mg concentrate for solution for infusion. 1 vial of 100 mg/ml.

Indication: The prophylaxis of migraine in adults who have at least 4 migraine days per month. Treatment should be initiated by a healthcare professional (HCP) experienced in the diagnosis and treatment of migraine. The infusion should be initiated and supervised by a HCP.

Dosage: The recommended dose is 100 mg administered by intravenous infusion every 12 weeks. Some patients may benefit from a dosage of 300 mg administered by intravenous infusion every 12 weeks. Assess need for dose escalation within 12 weeks after initiating treatment. When switching dosage, the first dose of the new regimen should be given on the next scheduled dosing date. Assess overall benefit and continuation of treatment 6 months after initiation. Elderly: No dose adjustment is required. Patients with renal/hepatic impairment: No dose adjustment required. Paediatric: The safety and efficacy of VYEPTI in children aged 6 to 18 years has not yet been established.

Route of administration: Intravenous infusion, after dilution of the vial content in 100 ml sodium chloride (0.9%) solution for injection. Following dilution infuse over approximately 30 minutes. Observe or monitor patients during and after the infusion in accordance with normal clinical practice. Do not administer as a bolus injection. See full SmPC for further details on administration.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings & Precautions: Traceability: To improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded. Cardiovascular risk: Patients with a history of cardiovascular disease (e.g. hypertension, ischaemic heart disease) were excluded from clinical studies. No safety data are available in these patients. Limited safety data are available in patients with cardiovascular risk factors such as diabetes, circulatory diseases and hyperlipidaemia. Neurological or psychiatric conditions: Patients with a history of neurological diseases or patients with psychiatric conditions that were uncontrolled and/or untreated were excluded from the clinical studies. Limited safety data are available in these patients. Serious hypersensitivity: Serious hypersensitivity reactions, including anaphylactic reactions, have been reported and may develop within minutes of the infusion. Most hypersensitivity reactions occurred during infusion and were not serious. 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. Hereditary Fructose Intolerance (HFI): VYEPTI contains sorbitol. Patients with HFI must not be given this medicinal product unless strictly necessary.

Interactions: Interactions by eptinezumab with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are considered unlikely.

Fertility, pregnancy and lactation: Limited data, as precautionary measure it is preferable to avoid VYEPTI during pregnancy. No data on the presence of eptinezumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be excreted in breast milk during the first few days after birth, which is decreasing to low concentrations soon afterward; consequently, a risk to the breast-fed infant cannot be excluded during this short period. Afterwards, use of eptinezumab could be considered during breast-feeding only if clinically needed. The effect of eptinezumab on human fertility has not been evaluated.

Undesirable effects: Common (≥1/100 to <1/10): nasopharyngitis, hypersensitivity reactions, infusion-related reaction, fatigue. Uncommon (≥1/1,000 to <1/100): anaphylactic reaction. Prescribers should consult the full SmPC in relation to other side effects.

Overdose: Symptomatic treatment with supportive measures instituted as required.

Legal category: POM.

Marketing Authorisation Holder:

Great Britain: Lundbeck Limited, Iveco House, Station Road, Watford, Hertfordshire, WD17 1ET, United Kingdom

Northern Ireland: H. Lundbeck A/S, 9 Ottiliavej, 2500 Valby, Denmark.

Marketing Authorisation Number:

Great Britain: PLGB 00458/0314 (1 vial), £1350.00.

Northern Ireland: EU/1/21/1599/001 (1 vial), £1350.00.

Further information is available from:

Lundbeck Limited, Iveco House, Station Road, Watford, Hertfordshire, WD17 1ET, United Kingdom. Tel. 01908 649966.

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VYEPTI® is a Registered Trade Mark.

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, Medical Information, on: 01908 638972 or Email: **SafetyLuUnitedKingdom@lundbeck.com**

vyepti® (eptinezumab) 100 mg/mL

Lundbeck