EMGALITY® ▼ (galcanezumab) PRESCRIBING INFORMATION

Presentation Emgality 120 mg solution for injection in pre-filled pen. Each pre-filled pen contains 120 mg of galcanezumab in 1 mL. The solution is clear and colourless to slightly yellow. Galcanezumab is a recombinant humanised monoclonal antibody produced in Chinese Hamster Ovary cells. **Uses** Emgality is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month. **Dosage and Administration** Treatment should be initiated by physicians experienced in the diagnosis and treatment of migraine. The instructions for using the pen included with the Package Leaflet, must be followed carefully. The pre-filled pen is for total use only. The pre-filled pen should be inspected visually prior to administration. Emgality should not be used if the solution is cloudy, discoloured or contains particles, or if any part of the device appears to be damaged. Do not shake. Posology The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose. Patients should be instructed to inject a missed dose as soon as possible and then resume monthly dosing. The treatment benefit should be assessed within 3 months after initiation of treatment. Any further decision to continue treatment should be taken on an individual patient basis. Evaluation of the need to continue treatment is recommended regularly thereafter. Special Populations *Elderly (> 65 years):* Galcanezumab has not been studied in elderly patients. No dose adjustment is required as the pharmacokinetics of galcanezumab are not affected by age. *Renal impairment/hepatic impairment:* No dose adjustment is required in patients with mild to moderate renal impairment or hepatic impairment. *Paediatric population:* The safety and efficacy of galcanezumab in children aged 6 to 18 years have not yet been established. No data are available. There is no relevant use of galcanezumab in children below the age of 6 years for the prevention of migraine. Method of administration Subcutaneous use. A patient may self-inject galcanezumab by following the Instructions for Use. Galcanezumab is to be injected subcutaneously in the abdomen, thigh, back of the upper arm, or in the gluteal region. After training, patients may self-inject galcanezumab if a healthcare professional determines that it is appropriate. Comprehensive instructions for administration are given in the Package Leaflet. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients (see SmPC for full details). **Warning and Special Precautions** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Cardiovascular risk:* Patients with certain major cardiovascular diseases were excluded from clinical studies. No safety data are available in these patients. *Serious hypersensitivity:* Serious hypersensitivity reactions including cases of anaphylaxis, angioedema and urticaria have been reported. If a serious hypersensitivity reaction occurs, administration of galcanezumab should be discontinued immediately and appropriate therapy initiated. **Interactions** No drug interaction studies were conducted. No pharmacokinetic drug interactions are expected based on the characteristics of galcanezumab. **Fertility, Pregnancy, and Lactation** *Pregnancy:* There are limited data from the use of galcanezumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Human immunoglobulin (IgG) is known to cross the placental barrier. As a precautionary measure, it is preferable to avoid the use of galcanezumab during pregnancy. *Breast-feeding:* It is unknown whether galcanezumab is excreted in human milk. Human IgG is known to be excreted in breast milk during the first days after birth, which is decreasing to low concentrations soon afterwards; consequently, a risk to breast-fed infants cannot be excluded during this short period. Afterwards, use of galcanezumab could be considered during breast-feeding only if clinically needed. *Fertility:* The effect of galcanezumab on human fertility has not been evaluated. Fertility studies in animals do not indicate harmful effects with respect to male and female fertility. **Effects on ability to drive and use machines** Galcanezumab may have a minor influence on the ability to drive and use machines. Vertigo may occur following the administration of galcanezumab. **Undesirable Effects** (See SmPC for more details) *Very common (≥ 1/10):* Injection site pain, Injection site reactions (Most frequently reported terms (≥ 1 %) were: Injection site reaction, Injection site erythema, Injection site pruritus, Injection site bruising, Injection site swelling). *Common (≥ 1/100 to < 1/10):* Vertigo, constipation, pruritus. *Uncommon (≥ 1/1,000 to < 1/100):* Urticaria (While urticaria is uncommon, serious cases of urticaria have been reported in galcanezumab clinical studies). *Rare (≥ 1/10,000 to < 1/1,000):* Anaphylaxis, Angioedema *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom:*** *http://www.medicines.org.uk/emc/* **Legal Category** POM **Marketing Authorisation Numbers (or Product Licence Numbers) and Holder** EU/1/18/1330/001 1 x Pre-filled Pen Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £386.50 per pack **Date of Preparation or Last Review:** December 2019 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: **UK:** + 44-(0) 1256 315000, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk

Adverse events and product complaints should be reported. Reporting forms and further information can be found at **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events and product complaints should also be reported to Lilly: please call **Lilly UK** on **01256 315 000**.