Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Teva UK Limited on +44 (0) 207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Ajovy®▼ (fremanezumab) 225mg Solution for Injection in Pre-filled syringe and Ajovy® (fremanezumab) 225mg Solution for Injection in Pre-filled Pen Abbreviated Prescribing Information. **Presentation:** Fremanezumab 225mg solution for injection in pre-filled syringe. Fremanezumab 225mg solution for injection in pre-filled pen. **Indications:** For prophylaxis of migraine in adults who have at least 4 migraine days *per* month. **Dosage and administration:** The treatment should be initiated by a physician experienced in the diagnosis and treatment of migraine. Ajovy is for subcutaneous injection only and can be injected into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, injection sites should be alternated. Patients may self-inject if instructed in subcutaneous self-injection technique by a healthcare professional. *Adults:* Two dosing options are available: *Monthly dosing:* 225mg once monthly. *Quarterly dosing:* 675mg every three months. When switching dosing regimens, the first dose of the new regimen should be administered on the next scheduled dosing date of the prior regimen. The treatment benefit should be assessed within 3 months after initiation of treatment. Evaluation of the need to continue treatment is recommended regularly thereafter. *Missed dose:* The indicated dose should resume as soon as possible, a double dose must not be administered to make up for a missed dose. *Children:* No data are available. *Elderly:* Limited data available. Based on the results of population pharmacokinetic analysis, no dose adjustment is required. *Renal impairment:* No dose adjustment is required. No data in severe renal impairment. *Hepatic impairment:* No dose adjustment is required. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. If a hypersensitivity reaction occurs, discontinue administration and initiate appropriate therapy. No safety data are available in patients with certain major cardiovascular diseases. **Interactions:** No formal clinical drug interaction studies have been performed. **Pregnancy and lactation:** It is preferable to avoid the use of Ajovy during pregnancy as a precautionary measure. A risk to the breastfed child cannot be excluded. A decision must be made whether to continue Ajovy therapy while breast-feeding. **Effects on ability to drive and use machines:** No influence on the ability to drive and use machines. **Adverse reactions:** Hypersensitivity reactions such as rash, pruritus, urticaria and swelling. *Very Common:* Injection site pain, injection site induration and injection site erythema. *Common:* Injection site pruritus. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** It is recommended that the patient be monitored for any signs or symptoms of adverse effects and given appropriate symptomatic treatment if necessary. **Legal category:** POM. **Marketing Authorisation Number:** EU/1/19/1358/001. **Marketing Authorisation Holder:** Teva GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany. **Job Code:** MED-IE-00017. **Date of Preparation:** January 2021.