NORTHERN IRELAND Prescribing Information: AIMOVIG® (erenumab) solution for injection in pre-filled pen

Important note: Before prescribing, consult Summary of Product Characteristics (SmPC).

Presentation: 70 mg solution for injection in pre-filled pen and 140 mg solution for injection in pre-filled pen. Each pre-filled pen contains 70 mg or 140 mg erenumab.

Indication(s): Aimovig is indicated for 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 recommended dose is 70 mg erenumab every 4 weeks. Some patients may benefit from a dose of 140 mg every 4 weeks. Each 140 mg dose is given either as one subcutaneous injection of 140 mg or as two subcutaneous injections of 70 mg. Clinical studies have demonstrated that the majority of patients responding to therapy showed clinical benefit within 3 months. Consideration should be given to discontinuing treatment in patients who have shown no response after 3 months of treatment. Evaluation of the need to continue treatment is recommended regularly thereafter. *Elderly (aged 65 years and over)* Aimovig has not been studied in elderly patients. No dose adjustment is required as the pharmacokinetics of erenumab are not affected by age. *Renal impairment / hepatic impairment* No dose adjustment is necessary in patients with mild to moderate renal impairment or hepatic impairment. *Paediatric population* The safety and efficacy of Aimovig in children below the age of 18 years have not yet been established. No data are available. Aimovig is for subcutaneous use. Aimovig is intended for patient self-administration after appropriate training.

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

Warnings/Precautions: *Cardiovascular diseases:* Patients with certain major cardiovascular diseases (pre-existing myocardial infarction, stroke, transient ischaemic attacks, unstable angina, coronary artery bypass surgery or other re-vascularisation procedures within 12 months prior to screening) were excluded from clinical studies. No safety data are available in these patients. *Hypersensitivity reactions:* Serious hypersensitivity reactions, including rash, angioedema, and anaphylactic reactions, have been reported with erenumab in post-marketing experience. These reactions may occur within minutes, although some may occur more than one week after treatment. In that context, patients should be warned about the symptoms associated with hypersensitivity reactions. If a serious or severe hypersensitivity reaction occurs, appropriate therapy should be initiated and treatment with erenumab should be discontinued. *Constipation:* Constipation is a common adverse reaction of erenumab and is usually mild or moderate in intensity. In a majority of the cases, the onset was reported after the first dose of erenumab; however patients have also experienced constipation later on in the treatment. In most cases constipation resolved within three months. In the post-marketing setting, constipation with serious complications has been reported with erenumab. In some of these cases hospitalisation was required, including cases where surgery was necessary. History of constipation or the concurrent use of medicinal products associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications. Patients should be warned about the risk of constipation and advised to seek medical attention in case constipation does not resolve or worsens. Patients should seek medical attention immediately if they develop severe constipation. Constipation should be managed promptly as clinically appropriate. For severe constipation, discontinuation of treatment should be considered. *Latex-sensitive individuals:* The removable cap of this medicinal product contains latex rubber. May cause severe allergic reactions.

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.

Interactions: No effect on exposure of co-administered medicinal products is expected based on the metabolic pathways of monoclonal antibodies. No interaction with oral contraceptives (ethinyl estradiol/norgestimate) or sumatriptan was observed in studies with healthy volunteers.

Fertility, pregnancy and lactation: There are a limited amount of data from the use of erenumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Aimovig during pregnancy. It is unknown whether erenumab is excreted in human milk. Human IgGs are known to be excreted in breast milk during the first few days after birth, which decreases to low concentrations soon afterwards; consequently, a risk to the breast-fed infant cannot be excluded during this short period. Afterwards, use of Aimovig could be considered during breast-feeding only if clinically needed. Animal studies showed no impact on female and male fertility.

Undesirable effects: Common (≥1/100 to <1/10): injection site reactions, constipation, muscle spasms, pruritus, and hypersensitivity reactions including anaphylaxis, angioedema, rash and swelling/oedema and urticaria. Most of the reactions in the registration studies were mild or moderate in severity. Less than 2% of patients in these studies discontinued due to adverse reactions. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing.

Legal classification: POM

Marketing Authorisation (MA) number, packs and NHS price (ex. VAT): MA number EU/1/18/1293/001 – 1 x 70 mg pre-filled pen: £386.50. MA number EU/1/18/1293/004 – 1 x 140 mg pre-filled pen: £386.50.

Date of last revision of prescribing information: August 2023

Full Prescribing Information available from: Novartis Pharmaceuticals UK Ltd, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Tel: 01276 692255.

NI | 247876-1| August 2023

Adverse Event Reporting:

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 Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report

If you have a question about the product, please contact Medical Information on 01276 698370 or by email atmedinfo.uk@novartis.com