AIMOVIG®

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

PRESENTATION:

70mg Solution for injection in pre-filled pen. Each pre-filled pen contains 70 mg (erenumab).

140mg Solution for injection in pre-filled pen. Each pre-filled pen contains 140mg (erenumab).

INDICATION:

Aimovig is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

DOSAGE:

Adults: Treatment is intended for patients with at least 4 migraine days per month when initiating treatment with erenumab. 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.

Pediatric patients: The safety and efficacy of Aimovig in children below the age of 18 years have not yet been established. No data are available.

Special populations:♦ *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.

Treatment should be initiated by physicians experienced in the diagnosis and treatment of migraine. Aimovig is for subcutaneous use. Aimovig is intended for patient self administration after appropriate training. The injection can be administered into the abdomen, thigh or into the outer area of the upper arm. Injection sites should be rotated and injections should not be given into areas where the skin is tender, bruised, red or hard.

CONTRAINDICATIONS:

♦Hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS:

♦ 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, initiate appropriate therapy and do not continue treatment with erenumab.♦Patients with certain major cardiovascular diseases were excluded from clinical studies. No safety data are available in these patients. ♦ In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. ♦ In

patients with latex sensitivity: The removable cap of the Aimovig pre-filled syringe/pen contains dry natural rubber latex, which may cause allergic reactions in individuals sensitive to latex.

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 (ethyl estradiol/norgestimate) or sumatriptan was observed in studies with healthy volunteers.

ADVERSE REACTIONS:

Common (≥1 to <10%): Hypersensitivity reactions including anaphylaxis, angioedema, rash, swelling/oedema and urticaria, Constipation, Pruritis, Muscle Spasms, Injection site reactions.

Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing.

PREGNANCY, LACTATION AND FERTILITY:

Pregnancy: There are a limited amount of data from the use of erenumab in pregnant women. As a precautionary measure, it is preferable to avoid the use of Aimovig during pregnancy. **Lactation:** It is unknown whether erunumab is excreted in human milk. Human IgGs are known to be excreted in breast milk during the first few days after birth, which is decreasing 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. **Fertility:** Animal studies showed no impact on female and male fertility.

LEGAL CATEGORY: POM

PACK SIZE: 1 pre-filled pen 70mg, 140mg

MARKETING AUTHORISATION HOLDER: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.

MARKETING AUTHORISATION NUMBER:

1 pre-filled pen 70mg (EU/1/18/1293/001)

1 pre-filled pen 140mg (EU/1/18/1293/004)

Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc., Representative Office Malta, P.O. Box 4, Marsa, MRS 1000, Malta. Tel: +356 21222872

2020-MT-AIM-13-FEB-2020

References:

1. Novartis Europharm Ltd. Aimovig Summary of Product Characteristics.
2. Goadsby PJ, Reuter U, Hallström Y, et al. A controlled trial of erenumab for episodic migraine. N Engl Med. 2017;377(22):2123-2132.
3. Tepper S, Ashina M, Reuter U, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. Lancet Neurol. 2017;16(6):425-434.
4. Buse DC, Lipton RB, Hallström Y, et al. Patient-reported outcomes from the STRIVE Trial: a phase 3, randomized, double-blind study of erenumab in patients with episodic migraine. Poster presented at: American Headache Society, 59th Annual Scientifi c Meeting; June 8–11, 2017; Boston, MA.
5. Lipton R, Tepper S, Reuter U, et al. Patient-reported outcomes in chronic migraine patients receiving placebo or erenumab (AMG 334) in a phase 2, randomized, double-blind study. Poster presented at: American Headache Society, 59th Annual Scientifi c Meeting; June 8–11, 2017; Boston, MA.