Aimovig **Important note:** Before prescribing, consult full prescribing information. **Presentation:** Solution for injection, subcutaneous use: 1 mL prefilled pen contains 70 mg of erenumab. **Indications:** Aimovig is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month. **Dosage and administration: Adults:** The recommended dose of Aimovig is 70 mg administered subcutaneously every 4 weeks. Some patients may benefit from a dosage of 140 mg every 4 weeks. Aimovig is intended for patient self-administration in the abdomen, thigh, or, if someone else is giving the injection, also into the outer area of the upper arm. Administration should be performed by an individual who has been trained to administer the product. The needle cover of Aimovig pre-filled pen contains dry natural rubber, which may cause allergic reactions in individuals sensitive to latex. 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. The entire contents of the Aimovig pre-filled pen should be injected. **Special populations Pediatric patients:** The safety and effectiveness of Aimovig has not been studied in pediatric patients. **Geriatric patients:** No dose adjustment is necessary 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. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Patients with certain major cardiovascular diseases were excluded from clinical studies. No safety data are available in these patients. **Pregnancy, lactation, females and males of reproductive potential: Pregnancy:** Safety has not been established. As a precautionary measure, it is preferable to avoid the use of Aimovig during pregnancy. **Lactation:** It is not known whether erenumab is present 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. **Females and males of reproductive potential:** Animal studies showed no impact on female and male fertility. **Adverse drug reactions: Common (1/100 to <1/10):** Injection site reactions, constipation, muscle spasm, pruritus. **Description of selected adverse reactions:** Injections site reactions include injection site pain, injection site erythema and injection site pruritus. A majority of injection site reactions were mild and transient. **Immunogenicity:** In pivotal studies the incidence of anti-erenumab antibody was 6.3% for the 70 mg dose (in-vitro neutralizing activity in 3 patients) and 2.6% for the 140 mg dose (no patients with in-vitro neutralizing activity). There was no impact of anti-erenumab antibody development on efficacy or safety of erenumab. **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. **Packs:** 1 mL prefilled pen contains 70 mg of erenumab. **Legal classification:** P1S1S3 Ref: EMA Aug 2018

References: 1. Aimovig™ Local Prescription Information 2019 . **2.** AshinaM, Goadsby PJ, Reuter U, et al. Long-term efficacy and safety erenumab in migraine prevention: results a 5-year, open-label treatment phase of a randomized clinical trial, EurJ Neurol 2021. dol: 10.1111/ene.14715 [Epubahead of print]

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Release the grip of migraine[1-2]

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Long-Term Efficacy and Safety of Erenumab in Migraine Prevention: Results from a 5-year, Open-Label Treatment Phase of a Randomized Clinical Trial

Background

- A 5-year (256-week) open-label treatment phase (OLTP) examined the long-term efficacy and safety of erenumab in North America and Europe
- Adult patients (aged 18–60 years) with episodic migraine (EM) who had successfully completed the 12-week double-blind treatment phase (DBTP) were eligible to participate in OLTP
- Patients initially received open-label erenumab 70 mg; following a protocol amendment dosage was increased to 140 mg

Study endpoints included change from baseline in

- MMD
- monthly AMSM in patients with baseline AMSM use
- HIT-6™
- MSQ (-RFR, -RFP, -EF)
- MIDAS (MIDAS total score, presenteeism, and absenteeism)
- Achievement of 50%, 75%, or 100% reduction from baseline in MMD
- Safety was assessed by monitoring AEs, vital signs, and development of anti-erenumab antibodies

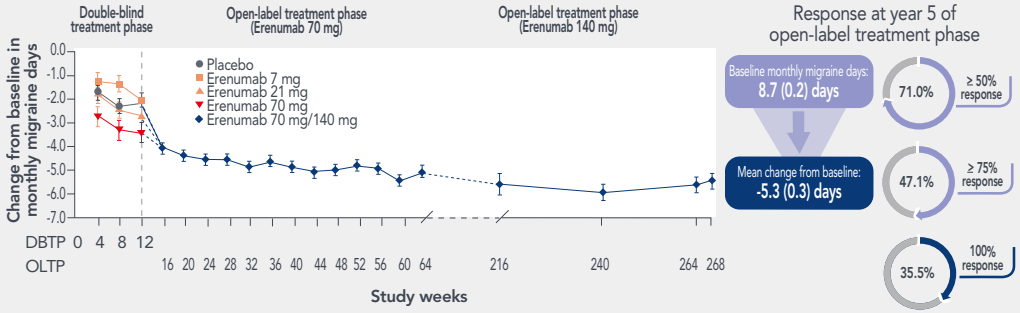
AEs, adverse events; AMSM, acute migraine-specific medication days; HIT-6, Headache Impact Test; MIDAS, Migraine Disability Assessment; MMD, monthly migraine days; MSQ, Migraine-Specific Quality-of-Life Questionnaire; RFR, role function-restrictive; RFP, role function-preventive; EF, emotional function

Summary of Results

- Of 383 patients enrolled, 250 switched to erenumab 140mg; 56.1% (215/383 patients) had completed open-label treatment
- Median (Q1, Q3) exposure to erenumab during the OLTP was 255 (68,256) week

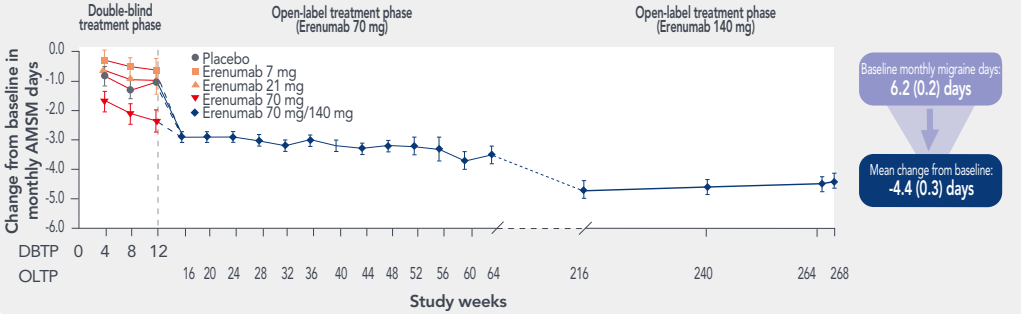
- At year 5, the mean MMD from baseline of 8.7 was reduced by 5.3 days (Figure 1A)

Figure 1A. Efficacy over time. Change from baseline in MMD



- Mean monthly AMSM use was reduced by 4.4 days at year 5 from baseline of 6.2 days among patients usiung AMSM (Figure 1B)

Figure 1B. Efficacy over time. Change from base line in AMSM days in patients with baseline monthly AMSM use



- Mean HIT-6™ total score at baseline was 60.2 and at Week 268 it improved to 49.4
- MSQ and MIDAS improvements from baseline were maintained through Week 268
- Of the 400 patients who received ≥1 dose of erenumab, the binding antibodies were developed in 39 patients (3 patients had developed in vitro neutralizing activity)

Conclusion: Erenumab treatment was associated with reductions in migraine frequency and improvements in health-related quality of life that were maintained for at least 5 years. No new safety signals or differences in incidence rates of AEs between OLTP and DBTP were observed