

Aimovig™ (erenumab-aooe) – New drug approval

- On May 17, 2018, the [FDA announced](#) the approval of [Amgen's Aimovig \(erenumab-aooe\)](#) for the preventive treatment of migraine in adults.
- Aimovig is the first FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of calcitonin gene-related peptide, a molecule that is involved in migraine attacks.
- The [2016 Global Burden of Disease Study](#) ranks migraine among the top 10 causes of years lived with disability worldwide. Migraine is three times more common in women than in men and affects more than 10% of people worldwide.
- Patients often describe migraine headache pain as an intense pulsing or throbbing pain in one area of the head. Additional symptoms include nausea and/or vomiting and sensitivity to light and sound. About one-third of affected individuals can predict the onset of a migraine because it is preceded by an aura. People with migraine tend to have recurring attacks triggered by a number of different factors (eg, stress, hormonal changes, bright or flashing lights, lack of sleep or food, and diet).
- The effectiveness of Aimovig for the preventive treatment of migraine was evaluated in three clinical trials, comparing Aimovig to placebo.
 - The first study included 955 patients with a history of episodic migraine. Over the course of 6 months, Aimovig-treated patients experienced, on average, 1 to 2 fewer monthly migraine days (MMDs) than those on placebo.
 - The second study included 577 patients with a history of episodic migraine. Over the course of 3 months, Aimovig-treated patients experienced, on average, 1 fewer MMD than those on placebo.
 - The third study evaluated 667 patients with a history of chronic migraine. Over the course of 3 months, Aimovig-treated patients experienced, on average, 2 ½ fewer MMDs vs. those receiving placebo.
- The most common adverse reactions (≥ 3% of treated patients and more often than placebo) with Aimovig use were injection site reactions and constipation.
- The recommended dose of Aimovig is 70 mg subcutaneously (SC) once monthly. Some patients may benefit from a dosage of 140 mg injected SC once monthly, which is administered as two consecutive SC injections of 70 mg each.
 - The SC injections should be administered in the abdomen, thigh, or upper arm.
- The list price of Aimovig is \$575 for once monthly 70 mg or 140 mg single-use prefilled SureClick® autoinjectors (ie, \$6,900 annually).
 - Amgen will also launch the [Aimovig Copay Program](#), which may be able to help reduce a patient's out-of-pocket costs for eligible patients with commercial insurance.

- Amgen plans to launch Aimovig within a week. Aimovig will be available in packs, containing one or two 70 mg/mL single-dose prefilled SureClick autoinjectors or prefilled syringes.



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