# Migraine Treatment of the Month

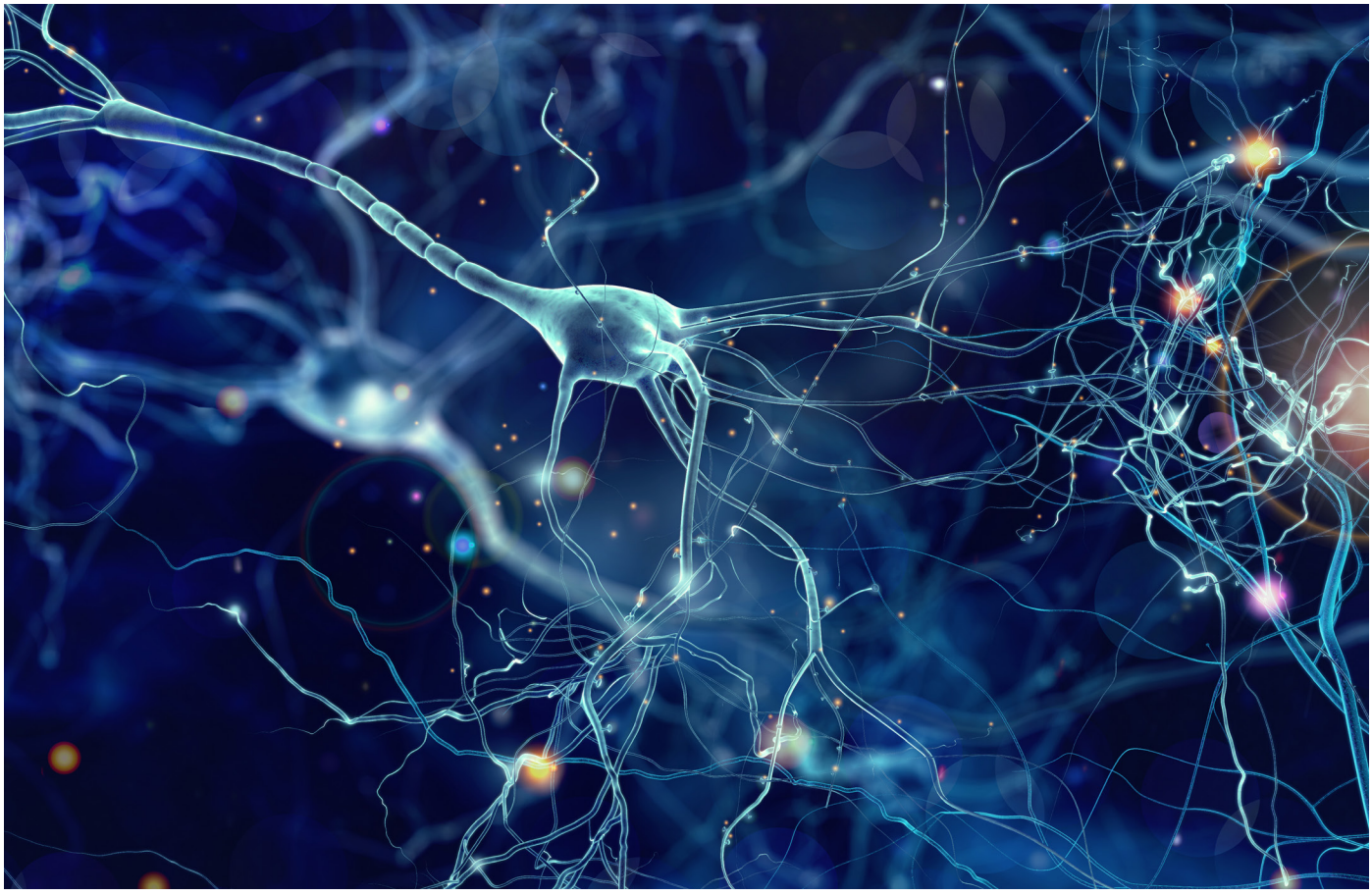
## *Atogepant (Qulipta)*

The nervous system is a complex collection of interactive electronic circuits that conduct communication signals along insulated wires that are called axons. As with any nervous system circuit, the biologic circuit that produces migraine headache conducts signal - in this case the signal of head pain - via electrochemical transmission. Put simply, an electronic signal travels down an axon, reaches a certain point, causes the release of a chemical, and that chemical interacts with its receptor either to pass the head pain signal along or to complete the circuit and produce the desired result…or in the case of migraine headache, the not so desired result.

While many different chemicals, most of them peptides (proteins), participate in migraine's circuitry, two of the most important chemical proteins within the circuit are serotonin and calcitonin gene-related peptide (CGRP). If one can block the contribution of either protein to the conduction of head pain signal, the sensitivity of the migraine circuit will be diminished, and the circuit's ability to produce headache consequently will decrease. It's like turning a light off by pressing a switch or turning down its brightness by adjusting a rheostat.

At present there are two major classes of anti-CGRP medications for migraine treatment: the monoclonal antibodies and the "gepants" (rimigepant/Nurtec, ubrogepant/Ubrelvy and, now, atogepant/Qulipta).

The anti-CGRP monoclonal antibodies (Mabs) are indicated for prevention/suppression of migraine and not for acute migraine treatment. Ubrelvy is indicated for acute migraine treatment



# don't let migraine steal your chance to say

# i am here

**Aimovig® is proven to reduce monthly migraine days.**

For some, Aimovig cuts the number of monthly migraine days in half or more.
So you can be there more.

Ask your doctor about Aimovig today.

## Approved Use

Aimovig® (erenumab-aooe) is a prescription medicine used for the preventive treatment of migraine in adults.

## Important Safety Information

### Who should not use Aimovig®?

Do not use Aimovig® if you are allergic to erenumab-aooe or any ingredients in Aimovig®.

**Before starting Aimovig®,** tell your healthcare provider (HCP) about all your medical conditions, including if you are allergic to rubber or latex, pregnant or plan to become pregnant, breastfeeding or plan to breastfeed.

Tell your HCP about all the medicines you take, including any prescription and over-the-counter medicines, vitamins, or herbal supplements.

### What are possible side effects of Aimovig®?

**Aimovig® may cause serious side effects, including:**

- **Allergic reactions.** Allergic reactions, including rash or swelling can happen after receiving Aimovig®. This can happen within hours to days after using Aimovig®. Call your HCP or get emergency medical help right away if you have any of the following symptoms of an allergic reaction: swelling of the face, mouth, tongue or throat, or trouble breathing.
- **Constipation with serious complications.** Severe constipation can happen after receiving Aimovig®. In some cases people have been hospitalized or needed surgery. Contact your HCP if you have severe constipation.
- **High blood pressure.** High blood pressure or worsening of high blood pressure can happen after receiving Aimovig®. Contact your healthcare provider if you have an increase in blood pressure.

The most common side effects of Aimovig® are pain, redness, or swelling at the injection site and constipation.

These are not all of the possible side effects of Aimovig®. Call your HCP for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

***Please see Brief Summary of the Patient Product Information on the next page.***

aimovig®
(erenumab-aooe) injection 70 mg/mL • 140 mg/mL

be there more™

connect with us

AMGEN® NOVARTIS

aimovig®
(erenumab-aooe) injection 70 mg/mL • 140 mg/mL

**BRIEF SUMMARY OF PATIENT INFORMATION**
**AIMOVIG® (AIM-oh-vig) (erenumab-aooe) injection, for subcutaneous use**

**What is AIMOVIG?**

- AIMOVIG is a prescription medicine used for the preventive treatment of migraine in adults. It is not known if AIMOVIG is safe and effective in children under 18 years of age.

**Who should not use AIMOVIG?**

- **Do not** use AIMOVIG if you are allergic to erenumab-aooe or any of the ingredients in AIMOVIG. See the end of this Patient Information for a complete list of ingredients in AIMOVIG.

Before you start using AIMOVIG, tell your healthcare provider about all your medical conditions, including if you are:

- **Allergic to rubber or latex.** The needle shield within the white or orange cap of the single-dose prefilled SureClick® autoinjectors and the gray needle cap of the single-dose prefilled syringes contain dry natural rubber.
- **Pregnant or plan to become pregnant.** It is not known if AIMOVIG will harm your unborn baby.
- **Breastfeeding or plan to breastfeed.** It is not known if AIMOVIG passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using AIMOVIG.

Tell your pharmacist or healthcare provider about all the medicines you take, including any prescription and over-the-counter medicines, vitamins, or herbal supplements.

**How should I take AIMOVIG?**

- **See the detailed "Instructions for Use" on complete information on how to take AIMOVIG.**
- Take AIMOVIG exactly as your healthcare provider tells you to take it.
- Before you inject, always check the label of your single-dose prefilled autoinjector or single-dose prefilled syringe to make sure you have the correct medicine and the correct dose of AIMOVIG.
- Also, before you inject, leave AIMOVIG at room temperature for at least 30 minutes protected from direct sunlight.
- AIMOVIG is injected under your skin (subcutaneously) 1 time each month.
- AIMOVIG comes in 2 different types of devices: a single-dose (1 time) prefilled autoinjector or a single-dose (1 time) prefilled syringe. Your healthcare provider will prescribe the type and dose that is best for you.
- If you forget to take AIMOVIG or are not able to take the dose at the regular time, take your missed dose as soon as you remember. After that, you can continue to take AIMOVIG 1 time each month from the date of your last dose.

**What are possible side effects of AIMOVIG?**
**AIMOVIG may cause serious side effects, including:**

- Allergic reactions. Allergic reactions, including rash or swelling can happen after receiving AIMOVIG. This can happen within hours to days after using AIMOVIG. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - o swelling of the face, mouth, tongue, or throat
  - o trouble breathing
- Constipation with serious complications. Severe constipation can happen after receiving AIMOVIG. In some cases, people have been hospitalized or needed surgery. Contact your healthcare provider if you have severe constipation.
- High blood pressure. High blood pressure or worsening of high blood pressure can happen after receiving AIMOVIG. Contact your healthcare provider if you have an increase in blood pressure.

The most common side effects of AIMOVIG include: pain, redness, or swelling at the injection site and constipation. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all of the possible side effects of AIMOVIG. Ask your pharmacist or healthcare provider for more information. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Amgen at 1-800-77-AMGEN (1-800-772-6436).

**How should I store AIMOVIG?**

- Store AIMOVIG in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep AIMOVIG in the original carton. This will protect the medicine from light.
- After removing AIMOVIG from the refrigerator, it can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 7 days.
- Throw away AIMOVIG that has been left at room temperature for more than 7 days.
- **Do not** freeze.
- **Do not** shake.

**Keep AIMOVIG and all medicines out of the reach of children.**

**General information about the safe and effective use of AIMOVIG.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use AIMOVIG for a condition for which it is not prescribed. **Do not** give AIMOVIG to other people, even if they have the same symptoms that you have. It can harm them. You can ask your pharmacist or healthcare provider for information about AIMOVIG that is written for healthcare professionals.

**What are the ingredients in AIMOVIG?**

- **Active Ingredient:** erenumab-aooe
- **Inactive Ingredients:** acetate, polysorbate 80, and sucrose.

The risk information provided here is not comprehensive. To learn more, talk about AIMOVIG with your healthcare provider or pharmacist. For the FDA-approved product labeling, call 1-800-77-AMGEN (1-800-772-6436) or visit www.aimovig.com.

AMGEN®

AIMOVIG® (erenumab-aooe)

**Manufactured by:**
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 U.S.A.
U.S. License No. 1080

**Marketed by:**
Amgen Inc. (Thousand Oaks, CA 91320)

Patent: http://pat.amgen.com/aimovig/

USA-334-84763

only. Nurtec occupies the unique position of being indicated for both acute migraine treatment and prevention of episodic migraine.

ADVANCE, the well-designed multi-center trial that evaluated Qulipta's safety, tolerability and effectiveness in the prevention of episodic migraine, demonstrated the medication to be safe, tolerable and robustly effective in reducing headache burden and migraine-related disability. Perhaps most striking, in those research subjects with episodic migraine who were destined to respond to Qulipta, a positive response often was observed within the first 1 to 2 weeks of initiating treatment. This tendency for early treatment response is not common amongst oral medications used for migraine prevention, and if this finding so clearly demonstrated in the ADVANCE study extends to general clinical practice, it will be attractive to both migraine patients and the physicians who care for them. Waiting weeks to months to determine whether or not a medication may be effective can be a tedious and frustrating process, and for a patient to experience the beginnings of a positive response so early in treatment can serve only as positive reinforcement for continuing the treatment.

**"...Qulipta represents a very attractive new option.**

Qulipta is available in 10, 30 and 60 mg dose formulations, each to be taken as one dose daily.

To put things in perspective, and rapidity of response aside, there is at most one other oral medication for prevention of episodic migraine, Nurtec, that is as well tolerated as Qulipta, as specific in its mechanism of action within the migraine circuitry and possessed of such a strong scientific evidence base for its use. A large scale clinical trial evaluating Qulipta's effectiveness in treating chronic migraine (link to Spring 2018 issue/vol 3, pg 5) was just completed, and its results should be forthcoming soon.

Which is better: Qulipta or a subcutaneously self-injected or intravenously administered anti-CGRP mab? How about Qulipta versus Nurtec? or Qulipta versus older therapies such as topiramate? In the absence of active comparator (ie, head-to-head) clinical trials, about the most that can be said at this point is that all of these medications are safe and effective for migraine prevention. Topiramate can be notoriously difficult to tolerate for a variety of reasons, but all of the others are generally well-tolerated by most patients.

Will Qulipta prove to be effective in patients who have failed to respond to an anti-CGRP Mab or Nurtec? Again, no one knows, but to extrapolate from the admittedly preliminary data concerning the anti-CGRP Mabs, an improvement in treatment response may be reported by patients who are switched from one anti-CGRP prevention medication to another.

Especially in dealing with a disorder as prevalent and as clinically varied as migraine, it's awfully nice to have options. For patients with episodic migraine who prefer an oral therapy for migraine prevention and for whom tolerability with a low chance of significant adverse side effects is important, Qulipta represents a very attractive new option. M