Migraine Europe The Strive to live well despite migraine



Urgent, Specialized Headache Care for Kids: TRUST THE EXPERTS

Although headaches are common in children, recurrent or frequent headaches that interfere with daily life are a concern to both parents and children.

At Children's National Health System, we care for more than 2,000 patients annually using a comprehensive and holistic approach to management, including lifestyle modification, behavioral strategies and advanced medications to alleviate your child's pain.





For urgent appointments, call 202-476-HEAD (4323) from 8:30 a.m. to 4:00 p.m. Monday through Friday to speak with a trusted headache expert.

The Headache Team offers the following services to their patients and families:

- Urgent headache appointments scheduled within five business days
- Interdisciplinary headache evaluations patients with chronic debilitating headaches have the option of seeing an interdisciplinary team of experts
- Headache infusions



111 Michigan Ave NW Washington, DC 20010

childrensnational.org







BOTOX® prevents headaches and migraines before they even start

On average 8 to 9 headache days and migraine/probable migraine days a month (vs 6 to 7 for placebo



*Restrictions and maximum savings limits apply. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. See full Terms and Conditions at BOTOXSavingsProgram.com.

*See Privacy & Terms: www.botoxsavingsprogram.com/eliqibility. Msq & data rates may apply. Msq Freq May Vary. Text HELP for help, STOP to end.

Indication

BOTOX® is a prescription medicine that is injected to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older.

It is not known whether BOTOX® is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing

Please see additional Important Safety Information on adjacent page.



Summary of Information about BOTOX® (onabotulinumtoxinA)

What is the most important information I should know about BOTOX®?

BOTOX $^{\odot}$ may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX $^{\odot}$:

- Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- Spread of toxin effects. The effect of botulinum toxin may affect
 areas away from the injection site and cause serious symptoms
 including: loss of strength and all-over muscle weakness,
 double vision, blurred vision and drooping eyelids, hoarseness
 or change or loss of voice, trouble saying words clearly, loss of
 bladder control, trouble breathing, and trouble swallowing

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat Chronic Migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.

What is BOTOX®?

BOTOX® is prescription medicine a medical professional injects into muscles to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years and older.

It is not known whether BOTOX® is safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

Who should not receive BOTOX®?

Do not receive BOTOX® if you are: allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); or have a skin infection at the planned injection site.

What should I tell my doctor before treatment?

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis (Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; plan to or have had surgery; have forehead muscle weakness such as trouble raising your eyebrows; drooping eyelids; or any changes to your face.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breast feed. It is not known if BOTOX® (onabotulinumtoxinA) can harm your unborn baby or if BOTOX® passes into breast milk.

What Are Common Side Effects?

The most common side effects include neck pain; headache; migraine; slight or partial facial paralysis; drooping eyebrows; eyelid drooping; bronchitis; musculoskeletal stiffness; muscular weakness; pain in 1 or more muscles, ligaments, tendons, or bones; muscle spasms; injection site pain; and high blood pressure. Other side effects have been reported including allergic reactions e.g. itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint.

These are not all of the possible side effects. Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

What Should I Tell My Doctor About Medicines and Vitamins I Take?

Using BOTOX® with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.** Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as Myobloc®, Dysport®, or Xeomin®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription and over-the-counter medicines, vitamins and herbal supplements you take; recent antibiotic injections; anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products; and blood thinners. Ask your doctor if you are not sure whether your medicine is listed above.

To Learn More

If you would like more information, talk to your doctor and/or go to BotoxChronicMigraine.com for full Product Information.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Based on v2.0MG1145 Rev. 06/2019

BCM69906-v3 10/19

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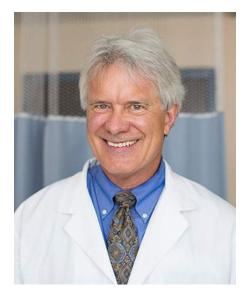
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Editor's Note

Migraineur's editor, Dr. John Rothrock, is professor and vice chair of neurology at the George Washington University School of Medicine.



This is the first issue of *Migraineur* published since last spring, a pause made necessary by the unprecedented emergence of so many new therapies for headache occurring over such a short period of time. Five new medications for migraine prevention, one also indicated for prevention of cluster headache, and four new medications for acute migraine

treatment. Nine new medications for migraine management! And all designed specifically for migraine...not recruited from the ranks of medications initially developed for hypertension, depression or epilepsy.

A lot to take in. When I decided to make this therapeutic revolution the central feature of the magazine's next issue, the revolutionary dust had not yet settled. Now, through our own research and clinical work at GW and that of clinical neuroscientists internationally, I feel we have had enough experience with this bounty to offer the readership the overview they deserve: a fair, balanced, realistic and informed description of how migraine's therapeutic landscape has changed.

Remember that all of our issues and blogs are posted on our website, migraineurmagazine.com. They are "open access", available to all for downloading and printing at no cost. Subscribe to the journal electronically and receive email notifications when new issues are published or new blogs or special announcements appear. Finally, if you have a question or comment or wish to contribute something from your own "migraine experience" to the magazine, contact our editorial office at edoffice@migraineurmagazine.com.

John F. Rothrock, MD

John F. Rothrock, MD, *Editor in Chief edoffice@migraineurmagazine.com*

IMPORTANT SAFETY INFORMATION (continued)

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat chronic migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

Do not receive BOTOX® if you: are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); have a skin infection at the planned injection site.

The dose of BOTOX® is not the same as, or comparable to, another botulinum toxin product.

Serious and/or immediate allergic reactions have been reported including itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX®.

Tell your doctor about all your medical conditions, including if you: have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX® passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you received BOTOX® in the past.

Tell your doctor if you received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as <code>Myobloc®</code>, <code>Dysport®</code>, or <code>Xeomin®</code> in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.

Other side effects of BOTOX® include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; and drooping eyebrows.

For more information refer to the Medication Guide or talk with your doctor.

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 refer to the Summary of Information about BOTOX® on the following page.



don't let migraine steal your chance to say

am

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.

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.

AMGEN® (b) NOVARTIS





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 erenumabaooe 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 overthe-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 singledose prefilled autoinjector or single-dose prefilled syringe to make sure you have the correct medicine and the correct dose of AIMOVIG.
- 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 singledose (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.

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 AlMOVIG 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[®] U NOVARTIS

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), and Novartis Pharmaceuticals Corporation (East Hanover, NJ 07936)

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Minuteman Press Bethesda mmbethesda.com

Publisher *Celerity Press*

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