

(Updated 2/6/22)

AJOVYTM (fremanezumab)

Ajovy, also known as fremanezumab, is a prescription medication by Teva for the preventive treatment of migraine in adults. Ajovy was FDA approved September 2018. This page is designed to answer some of the frequently asked questions about Ajovy, as well as provide some helpful resources. Ajovy is given as a self-administered pre-filled syringe or an auto-injector either monthly or quarterly.

IMPORTANT NUMBERS & WEBSITES(USA)

- Teva Customer Service Telephone: 800-545-8800
- Ajovy Nurse Line: 800-887-8100
- Ajovy Co-Pay Program Telephone: 800-671-3674
- Teva Cares Foundation Telephone: 877-237-4881 Fax: 877-438-4404 Hours: 9:00 AM 8:00 PM ET
- Shared Solutions Telephone: 800-887-8100 Fax: 844-257-6127 Hours: 8:00 AM 8:00 PM CT
- Ajovy Website: www.ajovy.com and www.ajovyhcp.com
- Shared Solutions Website: www.sharedsolutions.com
- Patient Advocate Foundation Migraine Matters: www.patientadvocate.org/migrainematters

MEDICATION INFORMATION

1. Does the Ajovy injection hurt?

A: Most patients say either it doesn't hurt at all or it has a little sting (less than with an Imitrex injection). However, your individual experience may be different. Bear in mind that some people prefer a pre-filled syringe while others prefer an autoinjector, so you may need to try both before deciding on which is best for you. The biggest negative we hear about pre-filled syringes is that you can see the needle, however they are often less painful than autoinjectors.

2. Where do I inject Ajovy?

A: There are three locations for this – the top of the thighs, the stomach, the upper arms.

3. How do I store/handle Ajovy?

A: Ajovy should be kept in the refrigerator (36-46°F, 2-8°C) until you are ready to use it. Keep it in the carton it comes in to protect from light. Then take it out and allow it to reach room temperature (68-77°F, 20-25°C) for at least 30mins immediately before injecting. Do not heat, freeze or shake it. Once at room temperature it cannot be put back in the fridge. After 24 hours at room temperature it needs to be discarded. Do not freeze, place in extreme heat or sunlight, or shake it. Please refer to the Ajovy website for details: www.ajovy.com

4. How often do I take Ajovy & do I self-inject or have my doctor do it?

A: There are two dosing options for Ajovy: Quarterly injections of 625mg (3 injections the same day) or monthly injections of 225mg. These injections can be done at home or in your doctor's office.

5. How long before I see results if it's going to work?

A: This varies greatly from patient to patient; some report results quickly, while for others it takes 2-3 months. A small percentage of patients experienced relief after the third dose when they did not earlier. For those who see at least some efficacy early on, that may continue to increase for up to six months.

6. Will Ajovy help my other aches, pains, fatigue, allodynia, light/sound/smell sensitivity?

A: This is unknown at this time since we don't have enough data, however doctors are optimistic about this since there was a definitive improvement in quality of life during the trials for those who responded.

7. Do I have to get this from a specialty pharmacy or do the mainstream ones also carry it?

A: Currently this medication should be available at all mainstream pharmacies. Please ensure that when you receive it the pharmacy has been keeping it in a refrigerator and that you immediately refrigerate it when getting home. If it reaches room temperature then it cannot be put back in the refrigerator and will need to be used within 24 hours.

8. Do I have to get my first injection at my doctor's office?

A: You don't have to do this unless your doctor requires it. The injection is designed to be simple to use, however, if you aren't used to self-injecting, you may want to do it at the doctor's office first.

9. What about my teenage son/daughter? Can they take this medication?

A: Ajovy is currently only approved in the USA for adults 18 years and older. If a doctor prescribes it to a teenager or other minor that would be off-label and a personal decision you make with that doctor. We are not aware of any current Ajovy trials for minors although this may change at any time.

10. What are the main differences between Ajovy and Aimovig?

Ajovy attaches to the CGRP peptide itself
Ajovy is more likely to cause hypersensitivity
Ajovy comes in a pre-filled syringe
Ajovy contains no latex in the syringe
Ajovy contains no latex in the syringe
Aimovig contains latex in the auto-injector cap

Ajovy offers co-pay & Shared Solutions programs Aimovig is offering a wide variety of programs

We have a document in our FILES that offers a more detailed comparison between the medications.

SIDE EFFECTS, SAFETY & CONTRAINDICATIONS

11. What are the known side effects?

A: The most frequently seen side effects in the clinical trials were allergic reaction and upper respiratory infections. Anecdotally, in real world use there appear to be several other side effects being seen by a small but significant number of patients including fatigue, constipation, hair loss, depression, anxiety, insomnia, worsening headache, joint pain, and GI symptoms.

12. What do I do if I think I'm getting a side effect not listed?

A: Contact your doctor and if the side effect is serious then consider reporting it to the FDA at https://www.fda.gov/safety/medwatch/. Please also let us know about side effects!

13. Can I take Ajovy with Botox or other migraine preventatives?

A: Currently there are no contraindications listed for Ajovy, including Botox. Always discuss with your doctor.

14. Can I take this with cardiovascular or other vascular problems?

A: There have not been clinical trials for this. Some reports state that it is not expected to cause problems, while others suggest Ajovy may have an impact. This is a decision to make with your doctor.

15. I got an injection site reaction from the injection. What can I do about that?

A: Injection site reaction is a listed side effect of Ajovy. Most of the reactions in the clinical trials were mild and temporary, however if you are having a moderate to severe reaction or you are concerned, please talk to your doctor's office immediately.

16. I think I'm hypersensitive to the injection. Is that possible and what should I do?

A: Hypersensitivity is a listed side effect of Ajovy for a small percentage of patients. If this happens to you with symptoms such as widespread itching or rash, please contact your doctor's office immediately. This reaction normally appears within hours to one month at most if you are going to get it. Often it is mild and temporary, but occasionally in the trials patients had to be treated with steroids.

17. Can I take this if I am pregnant, nursing, or planning to get pregnant or nurse?

A: There have been no clinical trials for pregnant or nursing women. It is currently unknow if or how Ajovy may impact the unborn child, or if it crosses into breast milk. It is suggested that you don't take Ajovy for 5-6 months if you plan to get pregnant since it takes 5-6 months to leave your system. Always discuss this with your doctor.

18. Can I take this if I am unable to take triptans due to their side effects?

A: Currently there is no listed contraindications regarding this. Triptans narrow blood vessels whereas CGRP medications do not appear to do that. We do not know the long-term side-effects yet.

19. Can I take this if I have medication overuse headache (MOH)?

A: According to some headache specialists, some MOH patients seem to be benefitting from CGRP and it is not contraindicated. However, bear in mind that MOH patients were excluded from clinical trials together with patients who had hemiplegic migraines, other pain syndromes such as fibromyalgia, vascular problems, etc.

INSURANCE – USA ONLY

20. What happens if my insurance requires a prior authorization (PA)?

A: Ajovy recommends the following for PAs: https://www.covermymeds.com/main/solutions/provider/ Feel free to suggest this to your doctor if they're not aware of it. You are your own best advocate and many doctor's offices are extremely busy, so any assistance you can provide may help the process.

21. I saw my doctor last week, two weeks ago, etc., and have not heard back. Now what?

A: You are your own best advocate. It's important to follow up with your doctor's office regularly to track the progress of the medication request and ensure they submitted the forms and information to get it approved.

22. What happens if my insurance denies Ajovy?

A: Your doctor should be working with your insurance to appeal any denial. Your insurance may require a Prior Authorization, <u>letter of medical necessity</u>, information about your medical history and more. It is possible to appeal multiple times when insurance denies coverage. Some doctor's offices are reluctant to file appeals because it is time consuming; sometimes you can help this process by being a "squeaky wheel" but other times you may need to submit the appeal(s) yourself. We have a document in our Files giving information on how to file an appeal yourself when necessary.

https://www.facebook.com/download/preview/437511106724266. If you have commercial insurance you can use the \$0 co-pay card in the meantime, while other patients can complete the Prescription and Service Request form to request assistance from Shared Solutions.

23. How long will it take for my insurance to cover Ajovy?

A: There is no set time for this. Some insurance companies cover it quickly, others may take a little while, and still others will fight it as long as they can! Many will require a prior authorization and/or a letter of medical necessity and some will need several appeals. We suggest staying on top of the approval process so your "paperwork" doesn't get lost in the mix.

Ajovy ACCESSIBILITY – USA ONLY

24. What is the \$0 Co-Pay Program?

A: This offers a \$0 co-pay for commercially insured patients, 18 years and older, in the USA. There is no registration required and you can <u>apply online yourself immediately</u>. Note: It is NOT available to patients who are eligible for coverage through Medicaid, Medicare, or other government healthcare programs such as Medigap, VA, Tricare & DOD. Also, if your insurance reimburses you in full for prescriptions you are not eligible. If you have questions about your eligibility, you can call: 800-671-3674

25. What is the Shared Solutions Prescription Assistance Program?

A: This program is a third party organization that is partnering with Teva for access to Ajovy. If you have any questions about accessing Ajovy, you can call them at 800-887-8100, 8am-8pm CT for assistance with prior approvals, reimbursement support, benefits verifications, insurance appeals, or administrative help. OR complete the Prescription & Service Request Form together with your doctor. You are responsible for completing sections 1-3 on page one including signing in section 3, and your physician completes sections 1-5 on page two including signing in section 5. We STRONGLY recommend that you get a copy of the completed and signed form from your doctor so that you can follow up if necessary. This form can be faxed to Shared Solutions at: 844-257-6127 or your doctor can submit it online at: www.iassist.com

26. What is the Teva Cares Foundation?

A: The details of this organization can be found here: www.tevacares.org Currently, Ajovy is not listed as a medication available through this foundation. The Foundation offers medications at no cost to patients in the USA who meet certain insurance and income criteria. Their telephone number is: 877-237-4881. You can call this number to ask about the latest news for Ajovy and whether it has been added to the covered medications list.

- 27. What if I am not eligible for either the Co-Pay Program or any program offered by Shared Solutions? If your insurance is denying Ajovy and you are not eligible for either of the above programs, you MAY be eligible for a reimbursement assistance program or other type of program to assist you if you cannot afford the medication. You can call TEVA Customer Service at 800-545-8800 for more information. You can also contact the <u>Patient Advocate Foundation at Migraine Matters</u> for free case management.
- 28. What other access resources are available so I can get this medication?

 The Patient Advocate Foundation offers free case management assistance through their Migraine Matters program. You can complete a request for assistance at www.patientadvocate.org/MigraineMatters. In addition, the Partnership for Prescription Assistance (PPARx) offers a single point of access to numerous patient assistance programs and healthcare resources. PPARx can be contacted at www.pparx.org or by calling 888-477-2669.
- 29. Are there any USA doctors close to me who are prescribing Ajovy?

A: We do not have information about specific doctor's prescribing practices, however if you are able to see a certified headache specialist it may be easier to access the medication. You can <u>click here to download or look at a list of every certified headache specialist</u> in the USA. If you are not able to see a certified headache specialist, which is true for most migraine patients, then we suggest finding a neurologist who is open to learning about these new medications.

HOPE FOR MIGRAINE GROUP INFORMATION

If you are not already a member you are welcome to join the **Hope for Migraine** group as well as our partner, **Migraine Meanderings**, for all things migraine.