



(Updated 2/6/22)

EMGALITY™ (galcanezumab)

Emgality, also known as galcanezumab, is a prescription medication by Eli Lilly for the preventive treatment of migraine in adults. Emgality was FDA approved September 2018. This page is designed to answer some of the frequently asked questions about Emgality, as well as provide some helpful resources. Emgality is given as a self-administered pre-filled syringe or auto-injector monthly with an initial higher loading dose.

IMPORTANT NUMBERS & WEBSITES (USA)

- Eli Lilly Customer Service Telephone: 800-545-5979
- Emgality Customer Service Telephone: 833-364-2548
- Emgality Co-Pay Program: Text "INFO" to 54559 for a co-pay program application
- Lilly Cares Foundation Telephone: 800-545-6962 Hours: 8:00 AM 8:00 PM ET
- Emgality Co-Pay Program Website: https://www.emgality.com/copay-card
- Emgality Website: www.emgality.com
- Lilly Cares Foundation Website: www.lillycares.com
- Report Side Effects To: www.fda.gov/medwatch or call: 800-FDA-1088

MEDICATION INFORMATION

1. Does the Emgality injection hurt?

A: Emgality is available in two different delivery mechanisms for your preference: auto-injection and pre-filled syringe. Many find that the injections don't hurt much, but your individual experience may be different. Bear in mind that Emgality comes in two different mechanisms, so if you have a strong preference you need to talk with your doctor. Some patients who experience pain or discomfort with auto-injectors may find the pre-filled syringe easier to tolerate. You can also try icing beforehand.

2. Where do I inject Emgality?

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

3. How do I store/handle Emgality?

A: Emgality should be kept in the refrigerator (36-46°F, 2-8°C) until you are ready to use it. Keep in the carton it comes in to protect from light. Then take it out and allow it to reach room temperature (68-86°F, 20-30°C) for at least 30 mins immediately before injecting. Do not heat, freeze or shake it. Once at room temperature it cannot be put back in the fridge. Emgality can be kept in its original container out of the refrigerator at temperatures up to (30°C) 86°F for 7 days maximum. After 7 days it needs to be discarded. Do not freeze, place in extreme heat or sunlight, or shake it. Please refer to the Emgality website for details: www.emgailty.com

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

A: Emgality is injected once a month with an initial higher dose the first time. The injections come in an auto-injector or pre-filled syringe. These injections can be done at home or in your doctor's office.

5. What should I do if I miss the date for my next Emgality injection?

You should take your missed dose as soon as possible. Going forward, take the next dose in one month.

6. How long does it take for to achieve maximum concentration of Emgality in the body after the injection?

It takes approximately 5 days to achieve maximum concentration. Injection site location did not significantly impact this time. It may take up to three months to take affect.

7. 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.

8. What is the half-life of Emgality?

The half-life is approximately 27 days.

9. Will Emgality 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.

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

A: This medication should currently be available at all mainstream pharmacies.

11. 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.

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

A: Emgality 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 Emgality trials for minors although this may change at any time.

13. What are the main differences between Emgality and Aimovig?

Emgality attaches to the CGRP peptide itself

Emgality comes in a pre-filled syringe & autoinjector

Emgality contains no latex in the syringe or autoinjector

Emgality has a co-pay program for commercial insurance patients

Aimovig attaches to the CGRP receptor site

Aimovig comes only in an auto-injector

Aimovig contains latex in the injector cap

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Aimovig softering a wide variety of programs

14. What are the main differences between Emgality and Ajovy?

Emgality comes in a pre-filled syringe & autoinjector. Ajovy only comes in a pre-filled syringe NOTE: Currently we are not aware of any other significant differences between the two medications. Both the efficacy and side-effects profiles were very similar. However, one medication may be effective for you while another may not, and the same may be true for potential side effects.

Click here for a comparison chart between Emgality, Ajovy and Aimovig

SIDE EFFECTS, SAFETY & CONTRAINDICATIONS

15. What are the known side effects?

A: The most frequently seen side effects in the clinical trials were allergic reaction and injection site reaction. 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. Please go to our Files section and look at the document titled, "Emgality Safety Side Effects Contraindications" for more details.

16. 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!

17. Can I take Emgality with Botox or other migraine preventatives?

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

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

A: There have not been clinical trials for this and is a decision to make with your doctor.

19. 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 Emgality. 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.

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

A: If you think you are having a reaction to the medication, please contact your doctor's office immediately.

21. Can I take Emgality if I have renal impairment?

Both renal and hepatic impairment are not expected to impact the pharmacokinetics of Emgality. In studies, neither creatinine clearance levels not bilirubin concentration impacted the pharmacokinetics in patients with mild to moderate renal impairment. However, there were no dedicated clinical studies for patients with mild to moderate renal or hepatic impairment. No studies were done with patients who have severe renal impairment.

22. 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 Emgality may impact the unborn child, or if it crosses into breast milk. It is suggested that you don't take Emgality for 5-6 months if you plan to get pregnant since it takes 5-6 months to leave your system. Discuss with your doctor!

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

A: Currently there are 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.

24. 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 inhibitor medication. 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

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

A: Your doctor should be able to easily submit a prior authorization together with any documentation asked for.

26. 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 information needed.

27. What happens if my insurance denies Emgality?

A: Your doctor should be working with your insurance to appeal any denial. Your insurance may require a Prior Authorization, letter of medical necessity, information about your medical history and more. It is possible to appeal multiple times when insurance denies coverage. Some doctors' 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

28. How long will it take for my insurance to cover Emgality?

A: There is no set time for this. Some insurance companies cover it quickly, while 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.

Emgality ACCESSIBILITY – USA ONLY

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

A: This offers a \$0 co-pay through December 31, 2020 for commercially insured patients, 18 years and older, in the USA. Text "INFO" to 54559 to apply immediately through your cell phone. 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 benefits or eligibility, you can call the Emgality Answers Center at: 833-364-2548. You can apply for this card online at: https://www.emgality.com/copay-card

30. What is the Lilly Cares Foundation?

A: The details of this organization can be found here: www.lillycares.com. This program is for those who are eligible patients and meet their criteria, who are either uninsured or have Medicare Part D (unfortunately Medicaid patients are not eligible). You can read information on the help available through the Lilly Cares Foundation here, and their online application form can be also be completed here. The Foundation offers medications at no cost to patients in the USA who meet certain insurance and income criteria. Their telephone number is: 800-545-6962.

31. Can I use the Emgality co-pay program if I have Medicaid or Medicare?

A: Unfortunately, this program is not available to patients with Medicaid or Medicare.

32. 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

<u>www.patientadvocate.org/MigraineMatters</u>. 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.

33. Are there any USA doctors close to me who are prescribing Emgality?

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.