Hope for Migraine
New & Emerging Treatments

Vyepti FAQs

(Updated 2/6/22)

VYEPTI™ (EPTINEZUMAB)

Vyepti, also known as eptinezumab, is a prescription medication by Lundbeck for the preventive treatment of migraine in adults. Vyepti was FDA approved on February 21, 2020. This page is designed to answer some of the frequently asked questions about Vyepti, as well as provide some helpful resources. Vyepti is given as an IV infusion in your doctor's office every three months. The infusion takes about 30 minutes.

IMPORTANT NUMBERS & WEBSITES (USA)

- Vyepti Customer Service Telephone: 833-489-3784
- Vyepti Co-Pay Program Website: https://www.Vyeptihcp.com/Vyepticonnect-support#financial-assistance
- Vyepti Website: www.Vyepti.com
- Lundbeck Patient Assistance Program Website: https://www.lundbeck.com/us/our-commitment/patient-assistance
- Lundbeck Patient Assistance Program Telephone: 833-800-0119
- Report Side Effects To: www.fda.gov/medwatch or Call: 800-FDA-1088

MEDICATION INFO

1. **Is Vyepti for both episodic and chronic migraine?**
   This medication was tested on both people with episodic migraine (1-14 days p/mth) and those with chronic migraine (15+ days p/mth). The PROMISE-1 trial included 665 patients, aged 18-71, who had migraine and headache 4-14 days per month. The PROMISE-2 trials included 1072 patients, aged 18-65, who had migraine and headache 15-26 days per month. Patients were allowed to use and to continue an established stable regimen of acute or preventive medication (except Botox). Patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute medication overuse (triptans, ergotamine, or combination analgesics greater than 10 days p/mth) were included. Both trials lasted 6 months. The studies excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease. Patients using opioids or butalbital-containing products greater than 4 days per month were excluded from the trials.
2. **In the trial for EPISODIC migraine, what reduction was seen in monthly migraine days?**
   100mg dose: 49.8% had at least 50% reduction; 22.2% had at least 75% reduction
   300mg dose: 56.3% had at least 50% reduction; 29.7% had at least 75% reduction
   Placebo dose: 37.4% had at least 50% reduction; 16.2% had at least 75% reduction
3. **In the trial for CHRONIC migraine, what reduction was seen in monthly migraine days?**
   100mg dose: 57.6% had at least 50% reduction; 26.7% had at least 75% reduction
   300mg dose: 61.4% had at least 50% reduction; 33.1% had at least 75% reduction
   Placebo dose: 39.3% had at least 50% reduction; 15.0% had at least 75% reduction
4. **How often do I take Vyepti and does this have to happen in my doctor's office?**
   A: Vyepti is administered via IV infusion once every three months. This infusion needs to be done at your doctor's office or medical facility by appointment.

5. **How long before I see results if it's going to work?**
   A: This varies greatly from patient to patient. Some clinical trial participants for Vyepti reported efficacy as soon as one day after the infusion. Similar to the other CGRP inhibitors, efficacy can continue to show over the first three months. As with any other medication, you may need to allow significant time to know if this is the right medication for you.
6. **What is the half-life of Vyepti?**
   The half-life is approximately 27 days.
7. **What about my teenage son/daughter? Can they take this medication?**
   A: Vyepti 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.
8. **What are the main differences between Vyepti and the CGRP inhibitor injectables?**
   Vyepti is administered via IV infusion at your doctor's office whereas Aimovig, Ajovy and Emgality are self-administered at home, via pre-filled syringe or autoinjector.
   Vyepti attaches to the CGRP peptide itself the same as Ajovy and Emgality, whereas Aimovig attaches to the CGRP receptor.
   Vyepti is given once every three months whereas Aimovig and Emgality are given monthly (Ajovy has the option of monthly or once every three months).
   NOTE: Currently we are not aware of any other significant differences between the medications. Both the efficacy and side-effect profiles are very similar, with Vyepti stating it can start taking effect as soon as day 1 after the infusion.

SIDE EFFECTS & CONTRAINDICATIONS

9. **What are the known side effects?**
   A: The most frequently seen side effects in the clinical trials were stuffy nose, scratchy throat, and allergic reaction. In clinical trials, only 1.9% of participants discontinued Vyepti due to side effects.
10. **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/ as well as to the pharmaceutical company.
11. **Can I take Vyepti with Botox or other migraine preventives?**
    A: In the clinical trials patients were allowed to use and continue an established stable regimen of preventive medication with the exception of Botox, which was excluded. Please discuss with your doctor whether Vyepti is a good option for you and whether it can be combined with Botox.
12. **Can I take this with cardiovascular or other vascular problems?**
    A: Patients with cardiovascular and cerebrovascular conditions were excluded from the clinical trials. Please discuss with your doctor whether Vyepti is a good option for you.
13. **I think I'm having an allergic reaction. 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 for medical advice. If it is an emergency situation, please call 911 or go to the nearest emergency room.
14. **Can I take Vyepti if I have renal or hepatic impairment?**
    No dedicated studies were conducted to assess the effects of renal or hepatic impairment on the pharmacokinetics of Vyepti. However, hepatic or renal impairment is not expected to affect the pharmacokinetics of Vyepti. A population pharmacokinetic analysis of integrated data from Vyepti clinical studies did not reveal clinically significant impact on pharmacokinetics of patients with hepatic or renal impairment.

15. **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 unknown if or how this medication may impact the unborn child, or if it crosses into breast milk. In order to allow the medication to completely leave your body you would need to wait about 5 months from the last dose since it has a 27 day half-life.
16. **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. Please discuss with your doctor whether this is a good treatment option for you.
17. **Can I take this with triptans?**
    In clinical trials, patients were allowed to use migraine-specific abortives including triptans and ergotamine derivatives. The co-administration of a single dose of 300 mg Vyepti administered as an intravenous infusion (over a period of 1 hour ± 15 min) with a single dose of 6 mg sumatriptan administered subcutaneously did not significantly influence the pharmacokinetics of Vyepti or sumatriptan.
18. **Can I take this if I have medication overuse headache (MOH)?**
    A: In the PROMISE-2 trial, patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute medication overuse (triptans, ergotamine, or combination analgesics greater than 10 days p/mth) were included.

INSURANCE (USA)

19. **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.
20. **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.
21. **What happens if my insurance denies Vyepti?**
    A: Your doctor should be working with your insurance to appeal any denial. Your insurance may require a prior authorization (PA), 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
22. **How long will it take for my insurance to cover Vyepti?**
    A: There is no set time for this. We expect some insurance companies to 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. Often it is the "squeaky wheel" that gets the oil!

ACCESS TO Vyepti (USA)

23. **Will Vyepti be available using prescription or medical benefits?**
    A: Some insurance companies approve it through prescription benefits, others through medical benefits, and some give patients the option so they can have the lowest out of pocket cost.

24. **If Vyepti is covered through prescription benefits, will a co-pay card be available?**
    A: Commercially insured patient can pay as little as $5 every 3 months using the Vyepti copay program. There is a maximum benefit of $4,000 per year. Click here for more information!
25. **Can I use the co-pay program (if available) with Medicaid, Medicare or TriCare?**
    A: Unfortunately, all manufacturer co-pay programs are inaccessible to patients with government-funded health insurance due to FDA regulations. However, depending on your income you may be eligible for Lundbeck's Patient Assistance Program.
26. **Is there a free trial for Vyepti?**
    A: At this point in time we are not aware of a free trial offer for Vyepti.
27. **What is the Lundbeck Patient Assistance Program (PAP)?**
    A: This program is for those who are eligible patients and meet their income criteria. To learn more about Lundbeck PAP, please call the toll-free number, 833-800-0119. You can also download the application here or learn more on their Patient Assistance website. The support center will assess each patient on a case-by-case basis.
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 Vyepti?**
    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 click here to download or look at a list of every certified headache specialist 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.

RESOURCES

https://www.Vyepti.com
https://www.lundbeck.com/upload/us/files/pdf/Products/Vyepti_PI_US_EN.pdf
https://www.businesswire.com/news/home/20200221005507/en/FDA-Approves-Lundbeck%E2%80%99s-Vyepti%E2%84%A2-eptinezumab-jjmr-%E2%80%93-Intravenous