



(Updated 2/22/22)

QULIPTA (atogepant)

QULIPTA (atogepant) is a prescription medicine by AbbVie used for the preventive treatment of episodic migraine in adults and is currently in phase 3 clinical trials for the preventive treatment of chronic migraine in adults. QULIPTA was FDA approved for episodic migraine on September 28, 2021, and it is currently available by prescription at pharmacies across the country. This page is designed to answer some of the more frequently asked questions about QULIPTA, as well as provide some helpful resources. QULIPTA is available as 10, 30 or 60 mg tablets.

IMPORTANT NUMBERS & WEBSITES (USA)

- Customer Service Telephone: 1-800-222-6885.
- Copay Savings Program: https://www.qulipta.com/savings-support/qulipta-complete-savings-program
- Access Programs: 1-800-222-6885
- Patient Assistance Program: https://www.abbvie.com/patients/patient-assistance.html
- Website: www.qulipta.com
- Report Side Effects To: www.fda.gov/medwatch or call: 800-FDA-1088

MEDICATION INFORMATION

1. What format does the medication come in?

A: QULIPTA comes in an oral tablet form.

2. How do I store/handle QULIPTA?

A: QULIPTA should be stored between 20°C and 25°C (68°F and 77°F): excursions permitted between 15°C and 30°C (59°F and 86°F).

3. How often may I take QULIPTA?

A: The recommended dose of QULIPTA is to take one (1) tablet, by mouth, each day with or without food. Take QULIPTA exactly as your healthcare provider tells you to.

4. How long does it take for QULIPTA to start working?

A: Clinical trials showed that QULIPTA can begin working as a preventive as early as day 1, however most of the impact starts between weeks 1-4 with reduction continuing up to 12 weeks.

5. What is the half-life of QULIPTA?

A: The half-life of QULIPTA is approximately 11 hours in healthy patients.

6. **Do I have to get this from a specialty pharmacy or do the mainstream ones also carry it?** A: QULIPTA is carried by mainstream pharmacies.

7. Is QULIPTA a controlled substance?

A: QULIPTA is not a scheduled or controlled substance.

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

A: QULIPTA 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.

SAFETY, SIDE EFFECTS & CONTRAINDICATIONS

9. What are the known side effects?

A: The most common side effects of QULIPTA as seen in the clinical trials are: nausea; constipation; fatigue; weight loss; and decreased appetite.

10. What do I do if I think I'm getting a serious side effect, or a side effect not listed?

A: If you are concerned about a side effect, please contact your doctor immediately. For urgent situations please go to urgent care or the ER. We also strongly recommend that any side effects needing medical care, a new medication, or cessation of QULIPTA be reported directly to AbbVie as well as the FDA at: https://www.fda.gov/safety/medwatch/. Please also let us know about side effects in the Hope for Migraine group on Facebook!

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

A: QULIPTA has not been shown to have any cardiovascular or vascular implications. However, please talk to your doctor about your specific condition and safety. We are unable to offer medical advice here.

12. Can I take QULIPTA if I have renal or hepatic impairment?

In patients with <u>severe</u> renal impairment or end-stage renal disease, it is recommended to take no more than 10 mg of QULIPTA daily. For patients with end-stage renal disease, it is recommended to take QULIPTA after dialysis. QULIPTA is safe for patients with mild or moderate renal impairment and for patients with mild or moderate hepatic impairment. Avoid use of QULIPTA if you have several hepatic impairment. Please talk to your doctor about your specific condition.

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

A: There is no adequate data on the developmental risk associated with the use of QULIPTA in pregnant women. According to the medication guide, animal data suggests that QULIPTA may cause fetal harm.

14. Are there any medications or substances which are contraindicated with QULIPTA?

A: QULIPTA is not contraindicated with any substances or medications, however modified dose recommendations with certain substances include: strong CYP3A4 inhibitors (recommended dose of 10mg daily), strong and moderate CYP3A4 inducers (recommended dose 30mg or 60mg daily), and OATP inhibitors (recommended dose 10mg or 30mg daily).

INSURANCE – USA ONLY

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

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

16. 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 to get it approved. You can also call your insurance company directly to help expedite the process.

17. What happens if my insurance denies QULIPTA?

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

18. How long will it take for my insurance to cover QULIPTA?

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!

QULIPTA ACCESSIBILITY – USA ONLY

19. Is there a copay card or savings program for QULIPTA?

A: There is a copay program that provides QULIPTA for as low as \$0/month for people with commercial insurance. You can access the <u>savings program HERE</u>.

20. I have government-funded insurance; am I eligible for any programs to access QULIPTA?

A: Due to FDA rules copay programs are not available to patients with government-funded health insurance such as Medicare, Medicaid and TriCare. However, AbbVie offers a patient assistance program to people who are otherwise unable to access their medications due to low income and lack of insurance coverage. Click here to learn more about My AbbVie Assist PAP program.

21. What is the Partnership for Prescription Assistance?

Patients who aren't eligible for the savings program can reach out to the Partnership for Prescription Assistance (PPARx)®. This is an independent organization that provides a single point of access to numerous patient assistance programs and healthcare resources. The program assists patients with meeting their healthcare needs for free or at a reduced cost. Resources include locating free and low-cost clinics in your area, identification of disease advocacy support programs and organizations dedicated to aiding with health insurance and access problems. PPARx does NOT provide free medicine, but rather connects individuals to healthcare support resources that may be able to assist them. Contact Information: https://www.pparx.org/ Or 1-888-4PPA-Now (1-888-477-2669). You can also contact the Patient Advocate Foundation Migraine Matters for free case management assistance at: www.patientadvocate.org/MigraineMatters.

22. Are there any USA doctors close to me who are prescribing QULIPTA?

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 find a list of every certified headache specialist in the USA on the resources page of our <u>website HERE</u>. 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 or one who is patient recommended.

HOPE FOR MIGRAINE GROUP INFORMATION

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

RESOURCES

https://www.quliptahcp.com/12-week-studies/12-week-efficacy QULIPTA medication guide