



# PREVENTS MIGRAINE DAYS AND KEEPS THEM AWAY OVER TIME

QULIPTA™ is a pill that significantly reduced monthly migraine days across 12 weeks in clinical studies

EXPLORE THE POSSIBILITY AT [QULIPTA.COM](https://www.qulipta.com)

LEARN MORE ABOUT HOW YOU MAY SAVE. TEXT ENROLL TO 785478

## WHAT IS QULIPTA™?

QULIPTA (atogepant) is a prescription medicine used for the preventive treatment of episodic migraine in adults.

## IMPORTANT SAFETY INFORMATION

Before taking QULIPTA, tell your healthcare provider about all your medical conditions, including if you:

- Have kidney problems or are on dialysis
- Have liver problems
- Are pregnant or plan to become pregnant. It is not known if QULIPTA will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if QULIPTA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking QULIPTA

Please see the Brief Summary of the full Patient Information on the following page.

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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. QULIPTA may affect the way other medicines work, and other medicines may affect how QULIPTA works. Your healthcare provider may need to change the dose of QULIPTA when taken with certain other medicines.

The most common side effects of QULIPTA are nausea, constipation, and fatigue. These are not all the possible side effects of QULIPTA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](https://www.fda.gov/medwatch) or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit [AbbVie.com/myAbbVieAssist](https://www.abbvie.com/myAbbVieAssist) to learn more.

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# QULIPTA™ (kew-LIP-tah) (atogepant) tablets, for oral use

**CONSUMER BRIEF SUMMARY**  
Consult Package Insert for  
Full Prescribing Information

## Patient Information

Read the Patient Information that comes with QULIPTA before you start taking it and each time you get a refill. There may be new information. This brief summary is not comprehensive and does not take the place of talking with your doctor about your medical condition or treatment. For a copy of the full Prescribing Information visit [www.QULIPTA.com](http://www.QULIPTA.com).

### What is QULIPTA?

QULIPTA is a prescription medicine used for the preventive treatment of episodic migraine in adults. It is not known if QULIPTA is safe and effective in children.

**Before you take QULIPTA tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems or are on dialysis.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if QULIPTA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if QULIPTA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking QULIPTA.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. QULIPTA may affect the way other medicines work, and other medicines may affect how QULIPTA works. Your healthcare provider may need to change the dose of QULIPTA when taken with certain other medicines.

Especially tell your healthcare provider if you take any of the following, as your healthcare provider may need to change the dose of QULIPTA:

• ketoconazole or itraconazole	• rifampin	• St. John's wort
• cyclosporine	• carbamazepine	• efavirenz
• clarithromycin	• phenytoin	• etravirine

Keep a list of medicines you take to show to your healthcare provider or pharmacist when you get a new medicine.

### How should I take QULIPTA?

- Take QULIPTA by mouth 1 time each day with or without food.
- Take QULIPTA exactly as your healthcare provider tells you to take it.

### What are the possible side effects of QULIPTA?

The most common side effects of QULIPTA include: nausea, constipation, and fatigue.

These are not all of the possible side effects of QULIPTA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### How should I store QULIPTA?

- Store QULIPTA at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep QULIPTA and all medicines out of the reach of children.**

### General information about the safe and effective use of QULIPTA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use QULIPTA for a condition for which it was not prescribed. Do not give QULIPTA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about QULIPTA that is written for health professionals.

### What are the ingredients in QULIPTA?

**Active ingredient:** atogepant

**Inactive ingredients:** colloidal silicon dioxide, croscarmellose sodium, mannitol, microcrystalline cellulose, polyvinylpyrrolidone vinyl acetate copolymer, sodium chloride, sodium stearyl fumarate, and vitamin E polyethylene glycol succinate.

### Manufactured by:

Forest Laboratories Ireland Ltd.  
Dublin, Ireland

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# What's New?

## *Developments from the front lines of migraine research*



### Atogepant for chronic migraine

1. Atogepant (*Qulipta*): an attractive new option for suppressing chronic migraine
2. Migraine "Rescue": don't like self-injection? how about a nasal spray?
3. Alzheimer's, Dementia and Migraine: where things presently stand
4. Migraine and Sex: an update and a stimulating(!) new avenue of research

[Atogepant \(\*Qulipta\*\)](#) is an orally administered anti-CGRP "[gepant](#)" which received FDA approval for prevention of [episodic](#) migraine in September 2020. The subsequent PROGRESS trial, a large-scale, multicenter and scientifically rigorous clinical research study, has demonstrated *Qulipta* to be safe, effective and generally well-tolerated when used for suppression

of [chronic migraine](#) as well. The drug has a favorable side effect profile, and those migraineurs who wouldn't mind shedding a few pounds might find intriguing the fact that about 25% of research patients taking *Qulipta* lost 7% or more of their body weight compared with migraineurs on other treatments or a placebo.

For those individuals with chronic migraine who prefer daily oral administration of a single pill over self-injection of an anti-CGRP mab once-monthly, intravenous infusions of *Vyepti* every 3 months or BotoxA administered by medical provider every 12 weeks, *Qulipta* is clearly an excellent alternative. Whether those who have failed to respond positively to these other therapies will do well with *Qulipta*

remains unknown and the subject of ongoing research.

### A new intranasal therapy is on the way

In late May the FDA accepted for review Biohaven's new drug application filing of intranasal *zavegepant* for the acute treatment of migraine. If approved, *zavegepant* will join *rimegepant* (*Nurtec*) in Biohaven's corral of migraine therapies and would represent the only FDA-approved CGRP antagonist in an intranasal formulation. Eliminating the need for gastrointestinal passage and absorption, nasal sprays typically offer patients with acute migraine more rapid relief than they experience with orally administered medication. For those with severe nausea accompanying the migraine headache, the intranasal administration offers another obvious advantage.

What to expect from this new option if and when it becomes available: the safety and high tolerability offered by a gepant with a rapidity of therapeutic action faster than that of orally administered medication but somewhat slower than that associated with subcutaneously self-administered sumatriptan.

### Alzheimer's, dementia and migraine

The arsenal of safe and effective pharmacologic therapies for acute migraine treatment and migraine prevention happily continues to expand. Sadly, the same cannot be said for Alzheimer's disease, another chronic neurologic disorder that produces a devastatingly negative impact on quality of life. In the absence of any meaningfully effective therapy, what *can* we do to assist in preventing and treating Alzheimer's? A related question: is migraine a risk factor for the development of dementia?

Can migraine cause dementia? While we must wait for a definitive answer and acknowledge that there are studies published in the peer-reviewed medical literature indicating an association

between migraine and dementia, there also exist a number of studies (as well as extensive clinical experience) suggesting that the cognitive symptoms and signs expressed and exhibited by patients with migraine - especially chronic migraine - may vanish with effective treatment of the migraine itself. In the editor's experience, his younger patients with

potential ethical misconduct in research involving Alzheimer's-related research, it is difficult to be as sanguine when considering therapeutic options for that awful disorder. In contrast to migraine, wherein the drugs we commonly prescribed 30 years ago (e.g., oral ergotamine tartrate/*Cafergot*) have given way to a veritable flood of new,

Association in San Diego in early August, the results of the EXERT study were presented. That study involved 296 sedentary subjects with "mild cognitive impairment" (MCI) and a mean age of 75. MCI implies a degree of cognitive disturbance greater than that expected for age but falling short of what would be expected with overt Alzheimer's. While not all individuals with MCI go on to develop Alzheimer's, it is a risk factor for developing progressive dementia of the Alzheimer's type. In EXERT the research subjects were given YMCA memberships and research subjects with MCI were given YMCA memberships and randomized to either a supervised regular aerobic exercise program or to a similarly supervised stretching and balance program. Their cognitive function was tested at baseline and then re-tested at 1 year. In contrast to a matched control group with MCI, no cognitive decline occurred in either exercise program subgroup.

Take-home message: physical exercise is good for the brain. If you want to protect your brain and decrease the chance of developing clinically disabling dementia, exercise your body, exercise your brain, socialize and stick to a healthy diet.

### Migraine and libido

Finally, to end on something of an up note let's turn our attention to the ever-compelling topics of sexual performance and desire, both in regards to migraine specifically and more generally in regards to the role of sex in the broader context of general health.

In a [previous issue](#) of this magazine we confronted the old cliché of "not tonight, darling. I have a headache" and its implication that migraineurs may have less of an appetite for sex than those unaffected by migraine. What researchers have found seems to indicate that, if anything, just the opposite is true. Both in terms of their sexual histories and from the results of testing intended to assess an individual's libido, migraineurs appear



chronic migraine and complaints of memory impairment and other cognitive disturbance sufficiently significant to interfere with daily activities and ability to work inevitably have experienced cessation of those cognitive issues when their migraine burdens were reduced or eliminated.

Especially in the wake of the recent and embarrassing revelations involving

more tolerable and more effective therapies, we still prescribe the same old minimally beneficial medications for Alzheimer's disease.

There did recently emerge some encouraging research data for a large portion of the population at increased risk for developing Alzheimer's. At the annual meeting of the Alzheimer's



to be both more active sexually and more libidinous than non-migraineurs. Investigating this issue with his colleagues, the editor of this magazine confirmed these findings that previously had been reported by others. In a recently conducted and more ambitious follow-up study which included female migraineurs not actively under medical care as well as migraineurs who were being evaluated and managed in a university-affiliated clinic, we found more or less the same: the research subjects with episodic migraine, whether actively under medical care or not, reported a level of libido, frequency of intercourse and likelihood of orgasm-associated intercourse that exceeded what was reported by age-matched controls free of migraine.

As to the issue of how a “successful” sex life may influence one’s general health, researchers at Cedars-Sinai Medical Center in Los Angeles, California are seeking women willing to use “sex toys for science.” Specifically, their study seeks to determine whether the current generation of vibrators –

powerful, technologically advanced, even Bluetooth-enabled – can improve sexual health, pelvic floor function and overall well-being.

Alexandra Dubinskaya, MD, the obstetrician who is leading the study, points out that results from previous studies generally have supported the use of vibrators to increase blood flow in pelvic tissues, improve sexual function (including orgasms), and possibly treat “stress” urinary incontinence by helping to strengthen the pelvic floor. Vibrator use also appears to boost desire, arousal, and genital sensation. Dr. Dubinskaya notes, “We have not had good-quality studies with the use of modern vibrators.” However one views such research, its relevance to our day-to-day lives is hard to overestimate.

In reviewing the literature that addresses these topics of sexual desire and sexual performance and conducting research in that area, I’m left with a question I find challenging. Just as it is no easy task to measure objectively a largely subjective

phenomenon such as a migraine headache or to identify an accurate and reliable means of measuring “[migraine burden](#)”, how does one measure “libido”? Just as is the case for assessing depression, there are a number of instruments used for scoring libido, but in the end...what is the gold standard? Frequency of intercourse? Genital performance? Frequency of orgasm? All of these are on most of the instruments that purport to measure libido, but just as migraine is “more than just a headache”, libido is much more than frequency of penetrative intercourse or achievement of orgasm. Like the blind men describing an elephant, each of these variables included on the instruments may be part of the greater whole...but only part. And the sum of those parts may not necessarily equal the whole.

Enough. Suffice it to say that however incomplete may be our current methods for measuring the blend of biologic and psychologic phenomena we name “libido”, migraineurs generally exhibit no deficiency in that area. **IV**