

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrQULIPTA®

atogepant tablets

This Patient Medication Information is written for the person who will be taking **QULIPTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **QULIPTA**, talk to a healthcare professional.

What QULIPTA is used for:

QULIPTA is used to prevent migraine headaches in adults who have at least 4 migraine days per month.

How QULIPTA works:

QULIPTA belongs to a group of medicines known as calcitonin gene-related peptide (CGRP) receptor antagonists. It works by blocking the action of a chemical in the body called CGRP that is linked to migraine headaches.

The ingredients in QULIPTA are:

Medicinal ingredient: atogepant.

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

QULIPTA comes in the following dosage form:

Tablets; 10 mg, 30 mg and 60 mg of atogepant.

Do not use QULIPTA if:

- you are allergic to atogepant, or any of the other ingredients in QULIPTA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take QULIPTA. Talk about any health conditions or problems you may have, including if you:

- have kidney problems or are on dialysis;
- have heart problems;

- have liver problems;
- are pregnant, think you might be pregnant or are planning to become pregnant. It is not known if QULIPTA will harm an unborn baby. A pregnancy registry is available for women taking QULIPTA during pregnancy. This registry collects information about your health and your baby's health. If you become pregnant while taking QULIPTA, talk with your healthcare professional about taking part in this registry. You can enroll in this registry at www.empresspregnancyregistry.ca, or by calling 1-844-467-0844;
- are breastfeeding or plan to breastfeed. Very small amounts of QULIPTA pass into breast milk. Your healthcare professional will help you decide the best way to feed your baby if you take QULIPTA;
- are 65 years of age or older.

Other warnings you should know about:

Driving and using machines: QULIPTA can cause fatigue and drowsiness. Do not drive, operate machinery, or do tasks that require special attention until you are certain that QULIPTA does not affect you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with QULIPTA:

- medicines used to treat bacterial infections (e.g., clarithromycin and rifampicin);
- medicines used to treat fungal infections (e.g., itraconazole and ketoconazole);
- medicines used to treat HIV (e.g., efavirenz and etravirine);
- medicines used to treat seizures and epilepsy (e.g., carbamazepine and phenytoin);
- cyclosporine, a medicine used to suppress the immune system following organ transplant;
- ubrogepant, a medicine used to treat migraines;
- St. John's wort, a herbal remedy commonly used to treat depression and mood disorders;
- curcumin (turmeric);
- feverfew (Tanacetum parthenium), a perennial herb.

How to take QULIPTA:

Take QULIPTA tablets by mouth exactly as your healthcare professional tells you to. QULIPTA must be taken one time each day and can be taken with or without food.

Do not use QULIPTA for a condition for which it was not prescribed. Do not give QULIPTA to anyone else, even if they have the same symptoms you have. It may harm them. You can ask your healthcare professional for information about QULIPTA.

Usual dose:

Your healthcare professional will determine the right dose of QULIPTA for you and how long you should take it. Do not stop taking QULIPTA without first speaking to your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much QULIPTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose of your medication, you can take the missed dose as soon as you remember. If it is almost time for your next dose, skip your missed dose and take the next dose of your medication at your regularly scheduled time. Do not take 2 doses at the same time to make up for a missed dose.

Possible side effects from using QULIPTA:

These are not all the possible side effects you may have when taking QULIPTA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of QULIPTA may include:

- common cold;
- constipation;
- decreased appetite;
- decrease in body weight;
- diarrhea;
- dizziness;
- drowsiness;
- facial swelling;
- fatigue;
- hives;
- infection of the kidneys, ureters, bladder or urethra (urinary tract infection);
- infection of the sinuses and throat (upper respiratory tract infection);
- inflammation of the sinuses (sinusitis) or stomach and intestines (gastroenteritis);
- life threatening allergic reaction;
- itching;
- nausea;

- rash;
- shortness of breath.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store QULIPTA tablets between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about QULIPTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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