

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

QULIPTA 10 mg, Tablets

QULIPTA 30 mg, Tablets

QULIPTA 60 mg, Tablets

The active ingredient and its quantity:

Each tablet contains:

QULIPTA 10 mg – atogepant 10 mg/tablet (equivalent to 10.3 mg of atogepant free base monohydrate)

QULIPTA 30 mg – atogepant 30 mg/tablet (equivalent to 30.9 mg of atogepant free base monohydrate)

QULIPTA 60 mg – atogepant 60 mg/tablet (equivalent to 61.8 mg of atogepant free base monohydrate)

See "Important information about some of the this medicine's ingredients" in section 2.

For the list of inactive ingredients, please see section 6 "Further Information" in this leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

What QULIPTA is used for

QULIPTA is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.

Therapeutic group: Analgesics, antimigraine preparations

How QULIPTA works

QULIPTA works by blocking the activity of the calcitonin gene-related peptide (CGRP) molecule which has been linked to migraine. This reduction in CGRP's activity reduces migraine.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to the active substance atogepant or any of the other ingredients of this medicine (for the list of inactive ingredients, see section 6).

Special warnings about using this medicine:

Talk to your doctor or pharmacist before taking QULIPTA, especially if you:

- have liver problems
- have kidney problems

Children and adolescents

This medicine is not intended for children and adolescents below the age of 18.

There is no information regarding the safety and efficacy of using this medicine in children and adolescents below the age of 18.

Interactions/Drug Interactions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, herbal medicines and supplements. Some medicines may increase the risk of getting side effects. Especially if you take any of the following, as your healthcare provider may need to change the dose of QULIPTA:

- medicines used to treat infections (e.g., ketoconazole, itraconazole, clarithromycin, rifampin)
- medicines that affect your immune system (e.g., ciclosporin)
- medicines used to treat seizures and other neurological disorders (e.g., phenytoin)
- certain herbal supplements (e.g., St. John's wort)
- medicines to treat HIV infections (e.g., efavirenz, zidovudine)
- medicine used to treat epilepsy (e.g., carbamazepine)

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking QULIPTA.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Pregnancy:

It is not known if QULIPTA will harm your unborn baby.

Breast-feeding:

It is not known if QULIPTA passes into your breast milk

Driving and using machines

QULIPTA is not expected to impact your ability to drive and use machines.

Important information about some of the this medicine's ingredients

QULIPTA contains sodium

This medicine contains 31.5 mg sodium (main component of cooking/table salt) in each 60 mg tablet. This is equivalent to 1.6% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains less than 1 mmol sodium (23 mg) per 10 mg and 30 mg tablet, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dose is 10 mg, 30 mg, or 60 mg taken orally once a day. Your doctor may tell you to take a lower dose if you are taking other medicines (listed in section 2) or if you have severe kidney problems.

Do not exceed the recommended dose.

How to take QULIPTA

Take the tablets with or without food.

Swallow the tablets whole with a glass of water.

There is no information regarding chewing, crushing and breaking the tablets.

If you have accidentally taken a higher dose of QULIPTA

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take QULIPTA

Do not stop using QULIPTA without talking to your doctor first. Your symptoms may return if you stop the treatment.

Do not take a double dose to make up for a forgotten tablet. Take your next dose at the usual time and consult with your doctor. Adhere to the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking QULIPTA

Do not stop using QULIPTA without talking to your doctor first. Your symptoms may return if you stop the treatment.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of QULIPTA may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common (may affect up to 1 in 10 people):

- Feeling sick to your stomach (nausea)
- Constipation
- Tiredness (fatigue) or sleepiness
- Decreased appetite

If a side effect has occurred, if any of the side effects worsen or if you experience a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appears on the carton package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Bottle pack: discard 59 days after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Polyvinylpyrrolidone/Vinyl acetate copolymer, mannitol, microcrystalline cellulose, sodium chloride, croscarmellose sodium, vitamin E polyethylene glycol succinate, sodium stearyl fumarate and colloidal silicon dioxide.

What the medicine looks like and contents of the pack

QULIPTA 10 mg tablets

QULIPTA 10 mg tablet is a white to off-white, round biconvex tablet debossed with "A" and "10" on one side.

QULIPTA 30 mg tablets

QULIPTA 30 mg tablet is a white to off-white, oval biconvex tablet debossed with "A30" on one side.

QULIPTA 60 mg tablets

QULIPTA 60 mg tablet is a white to off-white, oval biconvex tablet debossed with "A60" on one side.

The medicine supplied in bottles of 30 tablets or carton box of 4 tablets in blister.

Not all pack sizes may be marketed.

The bottle packaging is a child resistant package.

The bottle package contains a desiccant; do not swallow or remove it from the bottle.

- License holder and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel
- Manufacturer name and its address: Forest Laboratories Ireland Ltd., Clonshaugh Business and Technology Park, Clonshaugh, Dublin 17, D17, E400, Ireland
- Revised in 09.2022.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
 - QULIPTA 10 mg, 170-61-37169-99
 - QULIPTA 30 mg, 170-62-37170-99
 - QULIPTA 60 mg, 170-63-37171-99