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

Each tablet contains:
atogepant 10 mg (equivalent to 10.3 mg of atogepant free base monohydrate).

QULIPTA® 30 mg
Tablets

Each tablet contains:
atogepant 30 mg (equivalent to 30.9 mg of atogepant free base monohydrate).

QULIPTA® 60 mg
Tablets

Each tablet contains:
atogepant 60 mg (equivalent to 61.8 mg of atogepant free base monohydrate).

For the list of inactive ingredients, please see section 6 "Further Information" in this leaflet. See also "Important information about some of the medicine's ingredients" in section 2.

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/for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment/medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

QULIPTA is indicated for the preventive treatment of migraine in adults.

Therapeutic group: Antimigraine preparations, calcitonin gene related peptide (CGRP) receptor antagonist.

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). Allergic reactions may include: life-threatening allergic reaction (anaphylaxis) and difficulty breathing (see below "Special warnings about using this medicine").

Special warnings about using this medicine:
Before starting treatment with QULIPTA, tell your doctor if:

- you have liver problems.
- you have kidney problems or are on dialysis.

Serious Allergic (hypersensitivity) reactions including anaphylaxis:
Serious allergic reactions can happen when you take QULIPTA or days after. Serious reactions can include: anaphylaxis (life threatening allergic reaction), swelling of the mouth, lips or tongue, difficulty breathing, rash, itching or raised and itchy red bumps of the skin (hives). Stop taking QULIPTA and get emergency medical help right away, if you get any of the above mentioned reactions (see also section 4 "Side Effects").

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
If you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal supplements, you should inform the attending doctor or pharmacist.
QULIPTA may affect the way other medicines work, and other medicines may affect how QULIPTA works. Your doctor may need to change the dose of QULIPTA when taken with certain other medicines. Especially if you take any of the following:

- 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, topiramate)
- certain herbal supplements (e.g., St. John's wort)
- medicines to treat HIV infections (e.g., efavirenz, etravirine)
- medicine used to treat epilepsy (e.g., carbamazepine)

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

Pregnancy and breast-feeding
Pregnancy
Before taking QULIPTA, tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. It is not known if QULIPTA will harm your unborn baby.

Breast-feeding
Before taking QULIPTA, tell your doctor if you are breastfeeding or planning to breastfeed. It is not known if QULIPTA passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking QULIPTA.

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

Important information about some of the medicine's ingredients
QULIPTA contains sodium
This medicine contains 31.5 mg sodium (the 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 usual recommended dose is:
Episodic migraine:
10 mg, 30 mg, or 60 mg taken orally once a day.

Chronic migraine:
60 mg taken orally once a day.

Consult your doctor before starting treatment with Qulipta, if you are taking other medicines (listed in section 2) or if you have severe kidney problems. Follow your doctor's instructions.
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 splitting 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
If you forget to take the medicine at the appropriate time, 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.

Serious side effects:
QULIPTA can cause serious side effects, including:

- **Allergic (hypersensitivity) reactions, including anaphylaxis:** Serious allergic reactions can happen when you take QULIPTA or days after. Stop taking QULIPTA and get emergency medical help right away if you get any of the following symptoms, which may be part of a serious allergic reaction:
  - Swelling to the face, lips, or tongue
  - difficulty breathing
  - rash
  - itching
  - hives
  - life-threatening allergic reaction (anaphylaxis)

Common side effects (may affect up to 1 in 10 users):
- Feeling sick to your stomach (nausea)
- Constipation
- Tiredness (fatigue)/sleepiness
- Decreased appetite
- Dizziness

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

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

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

The medicine is supplied in bottles of 30 tablets or in a carton box of 4 tablets in a 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 November 2023 according to MoH guidelines.
- **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