Package leaflet: Information for the patient

AQUIPTA 10 mg tablets
AQUIPTA 60 mg tablets
atogepant

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What AQUIPTA is and what it is used for
2. What you need to know before you take AQUIPTA
3. How to take AQUIPTA
4. Possible side effects
5. How to store AQUIPTA
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1. What AQUIPTA is and what it is used for

AQUIPTA contains the active substance atogepant.

How AQUIPTA works
AQUIPTA 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 attacks.

What AQUIPTA is used for
AQUIPTA is used in adult patients to:
- treat an active migraine attack
- prevent migraine in those who have at least 4 migraine days per month

2. What you need to know before you take AQUIPTA

Do not take AQUIPTA
- If you are allergic to atogepant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking AQUIPTA, especially if you:
- have liver problems
- have kidney problems

Allergic reactions

Stop taking AQUIPTA and tell your doctor immediately if you experience any symptoms of an allergic reaction such as:
- difficulty breathing
- swelling of the face
- rash, itching, or hives

Some of these symptoms can occur several days after you take AQUIPTA.

Children and adolescents
Do not give this medicine to children or adolescents (under 18 years old) because the use of AQUIPTA has not been studied in this age group.

Other medicines and AQUIPTA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may increase the risk of getting side effects.

The following is a list of examples of medicines that may require your doctor to lower the dose of AQUIPTA:
- ketoconazole, itraconazole, voriconazole, clarithromycin, telithromycin, rifampicin (medicines used to treat fungal or bacterial infections)
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir (medicines used to treat HIV)
- ciclosporin (medicine that affects your immune system)
- telmisartan (medicine used to treat high blood pressure)

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

Pregnancy, breast-feeding and fertility
AQUIPTA is not recommended during pregnancy.

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.

Driving and using machines
AQUIPTA may make you feel sleepy. Do not drive or use machines if you are affected.

AQUIPTA 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 tablet, that is to say essentially ‘sodium-free’.

3. How to take AQUIPTA

Always take this medicine exactly as your doctor has told you. Speak to your doctor or pharmacist if you are not sure.

How much to take
The maximum dose per day is 60 mg.

For treatment of a migraine attack as needed, the recommended dose is 60 mg.

For prevention of migraine, the recommended dose is 60 mg 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. Speak to your doctor if you are undergoing dialysis.

How to take
AQUIPTA may be taken with or without food.

If you take more AQUIPTA than you should
If you have used more AQUIPTA than you should, tell your doctor.

If you forget to take AQUIPTA
If you take AQUIPTA for the prevention of migraine and forget to take it:
A missed dose should be taken straight away. If it is close to your scheduled next dose, do not take a double dose to make up for a forgotten tablet.

If you stop taking AQUIPTA
If you take AQUIPTA for the prevention of migraine, do not stop using it without talking to your doctor first. Your symptoms may return if you stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Stop taking AQUIPTA and contact your doctor immediately if you have any of the following symptoms, which may be part of a serious allergic reaction:
- difficulty breathing
- swelling of the face
- rash, itching, or hives

Other side effects
Tell your doctor or nurse if you notice any of the following side effects:

Common (may affect up to 1 in 10 people)
- feeling sick (nausea)
- constipation
- tiredness (fatigue) or sleepiness (somnolence)
- decreased appetite
- weight loss

Uncommon (may affect up to 1 in 100 people)
- increased levels of liver enzymes

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store AQUIPTA

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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. Contents of the pack and other information

What AQUIPTA contains
The active substance is atogepant.
- Each tablet contains either 10 mg or 60 mg of atogepant.
- The other ingredients are: Polyvinylpyrrolidone/Vinyl acetate copolymer, vitamin E polyethylene glycol succinate, mannitol, microcrystalline cellulose, sodium chloride, croscarmellose sodium, colloidal silicon dioxide and sodium stearyl fumarate.

What AQUIPTA looks like and contents of the pack

AQUIPTA 10 mg tablets
AQUIPTA 10 mg tablet is a white to off-white, round biconvex tablet debossed with “A” and “10” on one side.

AQUIPTA 60 mg tablets
AQUIPTA 60 mg tablet is a white to off-white, oval biconvex tablet debossed with “A60” on one side.

For packs of 2 tablets, each blister contains 2 tablets.

For packs of 7, 28 or 98 tablets, each blister contains 7 tablets.

Not all pack sizes may be marketed.

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