AQUIPTA Tablet 10mg, 60mg

Atogepant (10 mg, 60 mg)

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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.

How AQUIPTA works

AQUIPTA is thought to block the activity of the calcitonin/calcitonin gene related peptide (CGRP)-receptor family, which have been linked to migraine.

Before you use AQUIPTA

- When you must not use it

Do not take AQUIPTA

- if you are allergic to atogepant or any of the other ingredients of this medicine.

Pregnancy, breast-feeding and fertility

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.

If you are pregnant, you should not take AQUIPTA. If you are a woman who could become pregnant, you should use adequate contraception during treatment with AQUIPTA.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you will use AQUIPTA while breast-feeding.

- Before you start to use it

Talk to your doctor, pharmacist, or nurse before taking AQUIPTA if you have severe liver problems.

- Taking other medicines

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, clarithromycin, rifampicin (medicines used to treat fungal or bacterial infections)
- ritonavir (medicine used to treat HIV)
- ciclosporin (medicine that affects your immune system)

How to use AQUIPTA

AQUIPTA is for oral use. Do not split, crush, chew or break the tablet before swallowing. The tablets may be taken with or without food.

- How much to use

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

- When to use it

The maximum dose per day is 60mg.

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

For prevention of migraine, the recommended dose is 60 mg atogepant once a day.

Your doctor may tell you to take a lower dose if:
- you are taking other medicines
- you have severe kidney problems or you are undergoing dialysis.

- How long to use it

- If you take AQUIPTA for the prevention of migraine, do not stop taking 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 or pharmacist.

- If you forget to use it

If you take AQUIPTA for the prevention of migraine and forget to take it:
- Take it as soon as you remember.
- If you forget your dose for an entire day, just skip the missed dose and take a single dose as usual the following day.
- Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you have taken more tablets than you should, tell your doctor. You may get some of the listed side effects.

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While you are using it
- Things you must do
Take AQUIPTA exactly as your healthcare provider tells you to take it. Do not change your dose.

- Things you must not do
Do not use AQUIPTA for a condition for which it was not prescribed. Do not give AQUIPTA to other people, even if they have the same symptoms that you have. It may harm them.

- Things to be careful of

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.

Driving and using machines

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

AQUIPTA contains sodium

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

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

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 if you notice any of the following side effects:
Common (may affect up to 1 in 10 people)
- nausea (feeling sick in your stomach)
- constipation
- fatigue (tiredness)
- somnolence (sleepiness)
- decreased appetite
- weight loss

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AQUIPTA
- Storage
Store AQUIPTA at or below 30˚C.

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

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.

- Disposal
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.

Product Description
- What it looks like

AQUIPTA Tablet 10 mg is a white to off-white, round biconvex tablet debossed with "A" and "10" on one side. It is available in packs containing 28 tablets.

AQUIPTA Tablet 60 mg is a white to off-white, oval biconvex tablet debossed with "A60" on one side. It is available in packs containing 7 and 28 tablets.

- Ingredients

AQUIPTA Tablet 10 mg
- The active substance is atogepant. Each tablet contains 10 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.

AQUIPTA Tablet 60 mg
- The active substance is atogepant. Each tablet contains 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.

MAL number:
AQUIPTA Tablet 10 mg
MAL25046001ACRZ

AQUIPTA Tablet 10mg, 60mg

Atogepant (10 mg, 60 mg)

AQUIPTA Tablet 60 mg
MAL25046002ACRZ

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Clonshaugh Business and Technology
Park Clonshaugh, Dublin 17, Ireland

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