

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Aquipta?

Aquipta contains the active ingredient atogepant. Aquipta is used to prevent migraine in patients who have at least 4 migraine days per month.

For more information, see Section 1. Why am I using Aquipta? in the full CMI.

2. What should I know before I use Aquipta?

Check the list of ingredients at the end of the CMI. Do not use if you have ever had an allergic reaction to atogepant or any of the ingredients.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Aguipta? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Aquipta and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Aquipta?

- The recommended dose is 60 mg once a day. Swallow whole with a glass of water with or without food.
- Your doctor may tell you to take a lower dose if you are taking other medicines or if you have severe kidney problems

More instructions can be found in Section 4. How do I use Aquipta? in the full CMI.

5. What should I know while using Aquipta?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Aquipta.
Things you should not do	Do not stop taking this medicine or change the dose unless your doctor tells you to.
Driving or using machines	It is unlikely that Aquipta will have an effect on your ability to drive or use machines.
Drinking alcohol	There is no information of the effects of taking Aquipta with alcohol.
Looking after your medicine	Store it in a cool dry place, below 25°C, away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using Aquipta? in the full CMI.

6. Are there any side effects?

Serious allergic reactions with the use of Aquipta can occur with symptoms including difficulty breathing, swelling of the face, itching, rash, or hives.

Common side effects include decreased appetite, nausea, constipation, drowsiness (sleepiness) and tiredness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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Aquipta® (Ah-Quip-tah)

Active ingredient(s): Atogepant (ah-toh-gee-pant)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aquipta. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Aquipta.

Where to find information in this leaflet:

- 1. Why am I using Aquipta?
- 2. What should I know before I use Aquipta?
- 3. What if I am taking other medicines?
- 4. How do I use Aquipta?
- <u>What should I know while using Aquipta?</u>
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Aquipta?

Aquipta contains the active ingredient atogepant.

Aquipta belongs in a class of medicines called calcitonin gene-related peptide (CGRP) receptor antagonists. It works by blocking the activity of the molecule that has been linked to migraine.

Aquipta is used to prevent migraine in patients who have at least 4 migraine days per month.

2. What should I know before I use Aquipta?

Warnings

Do not use Aquipta if:

- you are allergic to atogepant, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have any liver or kidney problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 5. What should I know while using Aquipta? and Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Aquipta is not recommended during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

Aquipta is not recommended in children under 18 years of age. This is because it has not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Aquipta and affect how it works.

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.

- medicines used to treat infections (e.g., ketoconazole, itraconazole, clarithromycin, rifampicin)
- medicines that affect your immune system (e.g., cyclosporine)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Aquipta.

4. How do I use Aquipta?

How much to take

- 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 or if you have severe kidney problems.
- Follow the instructions provided and use Aquipta until your doctor tells you to stop.

When to take Aquipta

- Aquipta should be taken at about the same time each day.
- Aquipta can be taken with or without food.

If you forget to use Aquipta

Aquipta should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Aquipta

If you think that you have used too much Aquipta, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Centre (by calling 0800 POISON or 0800 764 766) or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Aquipta?

Things you should do

Call your doctor straight away if you:

- Become pregnant while taking Aquipta
- Experience any symptoms of an allergic reaction such as difficulty breathing, swelling of face, itching, rash, or hives

Remind any doctor, dentist or pharmacist you visit that you are using Aquipta.

Things you should not do

 Do not stop using this medicine or change the dose without checking with your doctor.

Driving or using machines

It is unlikely that Aquipta will have an effect on your ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information of the effects of taking Aquipta with alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Gut: Decreased appetite Feeling sick in your stomach (nausea) Constipation 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Brain:	
Drowsiness or sleepinessTiredness (fatigue)	

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction: • difficulty breathing • swelling of face • itching red rash or hives	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Aquipta contains

Active ingredient	Atogepant (as monohydrate)
(main ingredient)	
Other ingredients	Copovidone
(inactive ingredients)	Tocofersolan
	Mannitol

Microcrystalline cellulose
Sodium chloride
Croscarmellose sodium
Silicon dioxide
Sodium stearyl fumarate

Do not take this medicine if you are allergic to any of these ingredients.

What Aquipta looks like

Aquipta 10 mg tablets are white to off-white, round biconvex tablets. They have an "A" and "10" imprinted on one side.

Aquipta 60 mg tablets: are white to off-white, round biconvex tablets. They have an "A60" imprinted on one side.

Aquipta is supplied in blister packs inside a carton containing 7 or 28 tablets.

Who distributes Aquipta?

Distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

NEW ZEALAND

Tel: 0800 900 030

This leaflet was prepared in Jul 2024.

Version 02.

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