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Aquipta (*atogepant*)

An overview of Aquipta and why it is authorised in the EU

What is Aquipta and what is it used for?

Aquipta is a medicine used to prevent migraines in adults who have migraines at least 4 days a month.

Aquipta contains the active substance atogepant.

How is Aquipta used?

Aquipta is available as tablets to be taken by mouth once a day. It can only be obtained with a prescription.

For more information about using Aquipta, see the package leaflet or contact your doctor or pharmacist.

How does Aquipta work?

The exact way that Aquipta works is not fully understood. The active substance in Aquipta, atogepant, attaches to receptors (targets) for proteins called CGRP and amylin-1. These proteins are involved in the development of migraine. By attaching to these receptors, the medicine prevents CGRP and amylin-1 from binding to them. This helps prevent migraines from occurring.

What benefits of Aquipta have been shown in studies?

Aquipta was shown to reduce the number of days patients have migraines in two main studies.

In one study involving 882 patients who experienced at least 4 migraines a month, treatment with Aquipta for 12 weeks reduced migraines from around 8 days a month to around 3 to 4 days a month, compared with around 5 days for patients taking placebo (a dummy treatment).

In another study involving 760 patients who experienced at least 15 headache days a month with 8 out of these being migraine days, treatment with Aquipta for 12 weeks reduced migraines from around 19 days a month to around 12 days a month, compared with 14 days for patients taking placebo.

What are the risks associated with Aquipta?

For the full list of side effects and restrictions with Aquipta, see the package leaflet.

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The most common side effects with Aquipta (which may affect up to 1 in 10 people) include nausea (feeling sick), constipation, tiredness, somnolence (sleepiness), decreased appetite and decreased weight.

Why is Aquipta authorised in the EU?

Aquipta can reduce the number of days patients have migraines. Most of the side effects are mild or moderate in severity. Following concerns about a possible link to liver injury, an in-depth safety analysis provided reassurance about the medicine's liver safety profile. The European Medicines Agency therefore decided that Aquipta's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Aquipta?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Aquipta have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Aquipta are continuously monitored. Suspected side effects reported with Aquipta are carefully evaluated and any necessary action taken to protect patients.

Other information about Aquipta

Aquipta received a marketing authorisation valid throughout the EU on 11 August 2023.

Further information on Aquipta can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/aquipta.

This overview was last updated in 08-2023.