AQUIPTA®
(atogepant) tablets

MORE MIGRAINE-FREE DAYS^[1-3]

^Across 12 weeks, patients experienced more migraine-free days with AQUIPTA 60 mg vs. placebo.*[1-3]

***Episodic migraine** (OTHE population analysis): Significant -4.1 (52.5%) mean migraine day reduction from 7.8 baseline (n=226) vs. -2.5 (33.3%) from 7.5 baseline for placebo (n=216; $p<0.001$).[1] **Chronic migraine** (OTHE population analysis): Significant -6.8 (35.4%) mean migraine day reduction from 19.2 baseline (n=257) vs. -5.1 (26.8%) from 19.0 for placebo (n=249; $p<0.002$).[1]

AQUIPTA is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month[1]

SIMPLE ONCE-DAILY TABLET[1]

AQUIPTA tablets is an unfunded Prescription Medicine, on a private prescription. Patient charges for the medicine and healthcare professional fees may apply.

MIGRAINE IS MORE THAN A HEADACHE[4]

Migraine is a disabling disease that is often misunderstood and can have a considerable impact on patients and those around them[#4,5]

[#]My migraine voice survey – a large, cross-sectional online survey (from September 2017 – February 2018) conducted worldwide (31 countries across North and South America, Europe, the Middle East, Northern Africa, and the Asia-Pacific region) including 11,266 participants with migraine to assess the burden and impact of living with migraine from clinical, personal, and economic perspectives. Participants were ≥18 years of age with ≥4 MMDs and a history of preventive treatment failure.[5]

MIGRAINE IN NEW ZEALAND

About 750K people live with migraine in New Zealand[6]

WHAT CAUSES A MIGRAINE ATTACK?

While research into the exact mechanism that causes migraine is ongoing, calcitonin gene-related peptide (CGRP) is known to play a role.[7,8] During a migraine attack, CGRP levels increase and bind to CGRP receptors resulting in pain, inflammation, and vasodilation.[7-9]

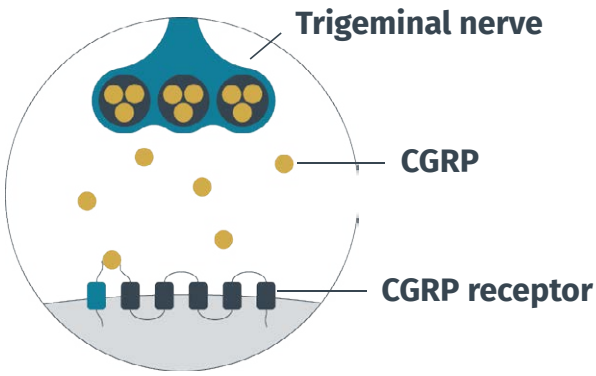
Tablet not actual size.

INTRODUCING AQUIPTA

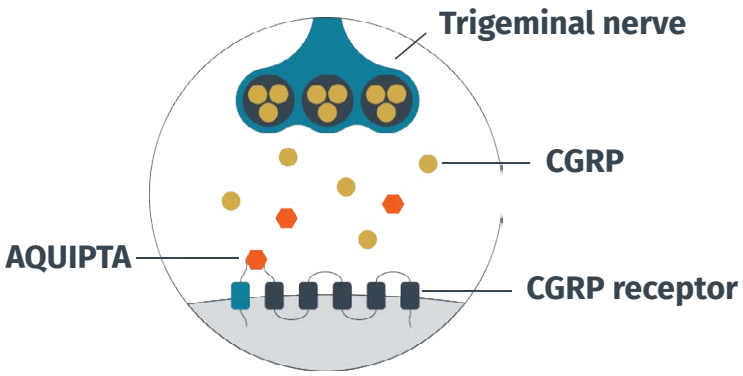
AQUIPTA is an oral preventative CGRP antagonist specifically designed to prevent migraine attacks in adult patients[1]

AQUIPTA INHIBITS THE SIGNALLING OF CGRP, A KEY MEDIATOR UNDERLYING MIGRAINE PATHOGENESIS[1,7-9]

CGRP ELEVATED DURING MIGRAINE



AQUIPTA BLOCKS CGRP FROM ATTACHING TO RECEPTORS



Adapted from Edvinsson L, *et al.*[8] For illustrative purposes only.

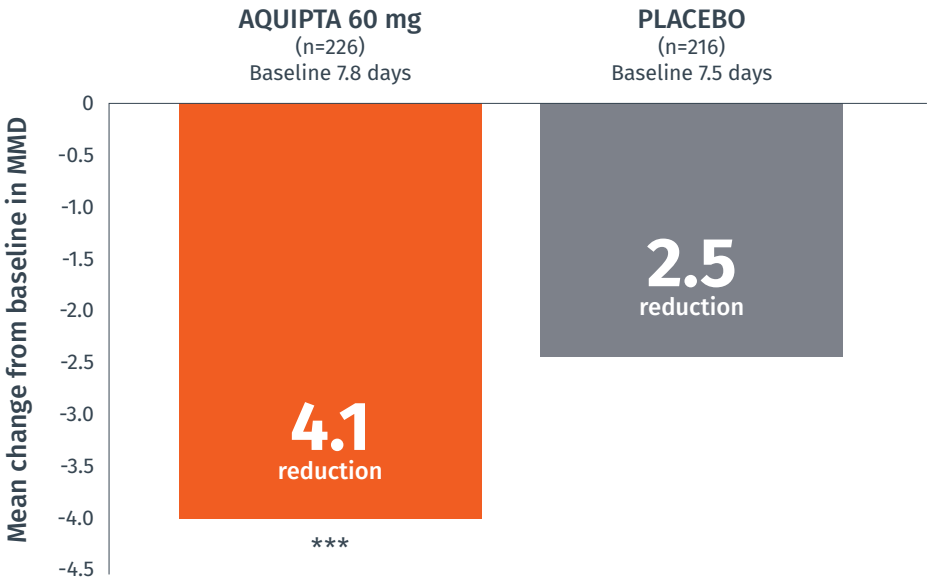
EFFICACY

AQUIPTA ACHIEVES CLINICALLY MEANINGFUL REDUCTIONS IN MONTHLY MIGRAINE DAYS (MMD)◆[1-3]

◆Across 12 weeks, AQUIPTA 60 mg significantly reduced attacks for both episodic and chronic migraine patients vs. placebo (p<0.001 and p<0.002, respectively).[1-3]

Episodic Migraine (4-14 migraine days per month)[1]

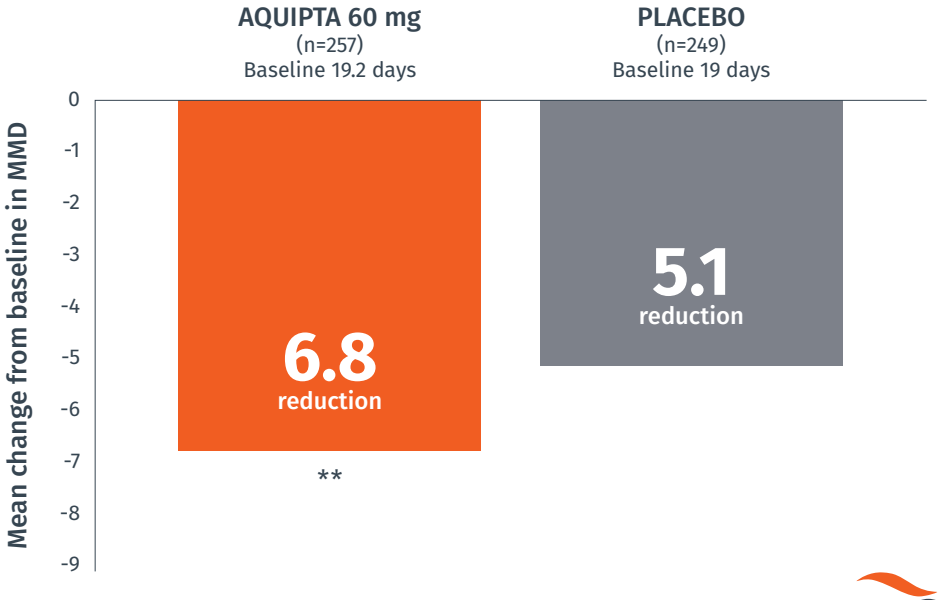
Primary endpoint (OTHE population analysis): Significant -4.1 (52.5%) mean migraine day reduction from 7.8 baseline (n=226) vs. -2.5 (33.3%) from 7.5 baseline for placebo (n=216); p<0.001 (ADVANCE trial)[1]



***p<0.001 vs. placebo.

Chronic Migraine (≥15 headache days per month with ≥8 migraine days)[1]

Primary endpoint (OTHE population analysis): Significant -6.8 (35.4%) mean migraine day reduction from 19.2 baseline (n=257) vs. -5.1 (26.8%) from 19.0 for placebo (n=249); p<0.002 (PROGRESS trial)[1]



**p<0.002 vs. placebo.

Refer to the study design at the end of this booklet.

AQUIPTA®
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AQUIPTA DELIVERS RAPID† AND SUSTAINED‡ EPISODIC MIGRAINE PREVENTION[1,2,10,11]

†Migraine day reductions seen as early as Day 1 post dose; 12.3% of AQUIPTA 60 mg patients (n=222) had a migraine day vs. 25.2% of placebo patients (n=214) after the initial dose.[10] ‡~84% of patients taking AQUIPTA 60 mg achieved >50% MMD reduction at weeks 49-52 (n=335; Open-label, Long-term Safety Study Design, efficacy analysis exploratory)[1,11]

Episodic Migraine

~88%

of patients did not have a migraine day vs. ~75% with placebo (ADVANCE trial)§[10]

§Proportion of participants with a migraine day on Day 1 after the first dose: 12.3% of AQUIPTA 60 mg patients (n=222) had a migraine day vs. 25.2% of placebo patients (n=214).[10]

Non-specified, non-ranked endpoints; not adjusted for multiplicity. Therefore, treatment differences cannot be regarded as statistically significant.

~53%

reduction in weekly migraine days for patients taking AQUIPTA 60 mg vs ~16% for placebo (ADVANCE trial)¶[10]

¶Change in baseline in weekly migraine days (WMD): Week 1 AQUIPTA 60 mg -1.0 WMD from 1.9 baseline (n=222); Week 1 placebo: -0.3 WMD from baseline 1.9 baseline (n=214).[10]

Non-specified, non-ranked endpoints; not adjusted for multiplicity. Therefore, treatment differences cannot be regarded as statistically significant.

Secondary endpoint:

~59%

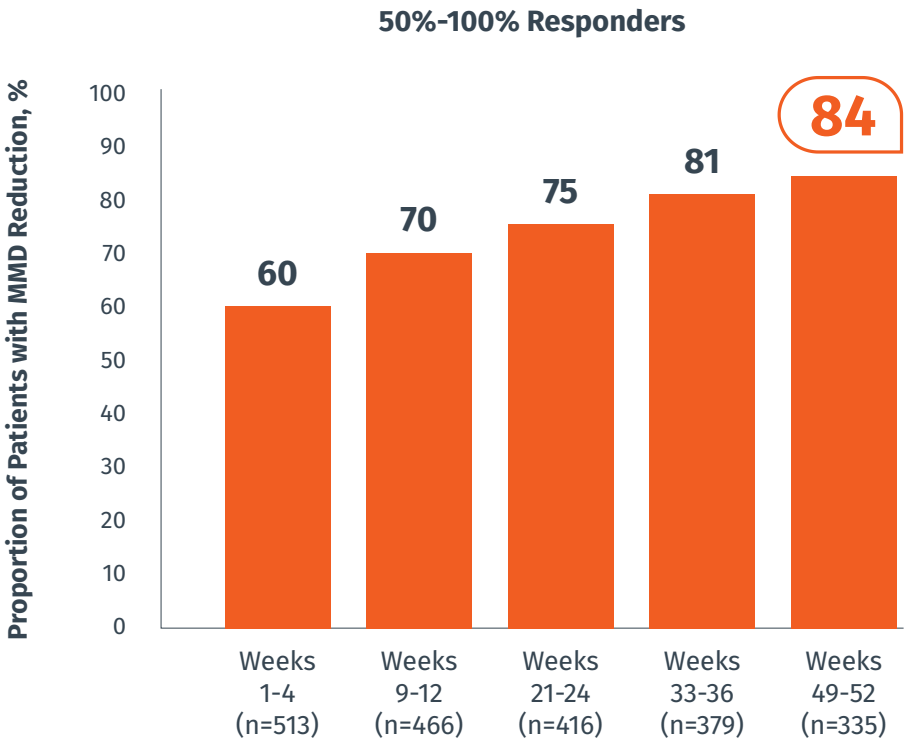
of patients taking AQUIPTA 60 mg (n=226) achieved a ≥50% **reduction in 3-month average of MMD** per month across 12 weeks vs. placebo (~29%; n=216; *p*<0.001; OTHE population analysis; ADVANCE trial)[1]

~84%

of patients taking AQUIPTA 60 mg **achieved >50% MMD reduction** at weeks 49-52 (n=335)[1,11]

This observation is from the 52-week, open-label safety study for which efficacy measures were not an endpoint.

Across 1 year[11]



In Weeks 49-52

84%

of patients achieved at least 50% MMD reduction††[11]
(n=335)

††These observations are from the 52-week, open-label safety study for which efficacy measures were not an endpoint. Efficacy assessments performed on the modified intent-to-treat population, which included participants with an evaluable baseline period of eDiary data and ≥1 evaluable postbaseline 4-week period of eDiary data.[11]

CHRONIC MIGRAINE - ACROSS 3 MONTHS

~40% of patients taking AQUIPTA 60 mg (n=257) achieved a ≥50% reduction in mean number of migraine days per month from baseline vs. ~27% with placebo across 12 weeks (n=249; *p*=0.002; secondary endpoint; PROGRESS trial)[1]

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TOLERABILITY & SAFETY PROFILE

A WELL-TOLERATED MIGRAINE PREVENTION TREATMENT OPTION FOR YOUR PATIENTS THAT YOU CAN PRESCRIBE WITH CONFIDENCE[1–3,11]

AQUIPTA was well-tolerated in clinical trials for episodic and chronic migraine[‡‡1-3]

‡‡The most commonly reported adverse drug reactions were:

- Nausea (7%), constipation (7%), and fatigue/somnolence (5%).
- The majority of the cases were mild, and none were serious.
- The adverse reaction that most commonly led to discontinuation was nausea (0.6%).
- 3.1% (21/663) of patients with placebo vs. 3.1% (21/678) with AQUIPTA 60 mg discontinued due to adverse events.[12]

The safety of AQUIPTA was evaluated in 2657 patients with migraine who received at least one dose of AQUIPTA. Of these, 1225 patients were exposed to AQUIPTA for at least 6 months, and 826 patients were exposed for 12 months.

In 12-week, placebo-controlled clinical studies, 314 patients received at least one dose of AQUIPTA 10 mg once daily, 411 patients received at least one dose of AQUIPTA 30 mg once daily, 343 patients received at least one dose of AQUIPTA 30 mg twice daily, 678 patients received at least one dose of AQUIPTA 60 mg once daily, 91 patients received at least one dose of AQUIPTA 60 mg twice daily, and 663 patients received placebo.

The table below lists adverse reactions for which a causal relationship between AQUIPTA and the adverse event is at least a reasonable possibility.

The adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), or very rare (<1/10,000).

Adverse drug reactions identified with AQUIPTA[1]

System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Not known	Hypersensitivity (e.g., rash, pruritus, urticaria, facial oedema)
Metabolism and nutrition disorders	Common	Decreased appetite
Gastrointestinal disorders	Common	Nausea, constipation
General disorders and administration site conditions	Common	Fatigue/somnolence

Contraindications[1]

AQUIPTA is contraindicated in patients with a history of hypersensitivity to atogepant or any of the components of AQUIPTA. Reactions have included anaphylaxis and dyspnea.

Special warnings and precautions for use[1]

- AQUIPTA 10 mg tablets contain less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. AQUIPTA 60 mg tablets contain 31.5 mg sodium per dose; this is equivalent to 1.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.[§§]
- Hypersensitivity reactions, including anaphylaxis, dyspnea, rash, pruritus, urticaria, and facial edema, have been reported with use of AQUIPTA.

Liver enzyme elevations[1]

In placebo-controlled studies, the rate of transaminase elevations over 3 times the upper limit of normal was similar between patients treated with AQUIPTA (0.9%) and those treated with placebo (1.2%).

There were cases with transaminase elevations over 3 times the upper limit of normal that were temporally associated with AQUIPTA treatment; these were asymptomatic and resolved within 8 weeks of discontinuation.

There were no cases of severe liver injury or jaundice in placebo-controlled studies.

Changes in body weight[1]

In placebo-controlled studies, the proportion of patients with a weight decrease of at least 7% at any point was 2.5% for placebo, 3.8% for AQUIPTA 10 mg once daily, 3.2% for AQUIPTA 30 mg once daily, 5.3% for AQUIPTA 30 mg twice daily, 5.3% for AQUIPTA 60 mg once daily, and 6.8% for AQUIPTA 60 mg twice daily.[§§]

[§§]Only AQUIPTA 60 mg presentation is available in NZ.

Please refer to the full Data Sheet for details full information.

AQUIPTA DOSING

Simple once-daily tablet[1]

The recommended dose for AQUIPTA is 60 mg taken orally once daily with or without food.[1]

Store in a cool dry place, below 25°C, away from moisture, heat, or sunlight[1]

Taken with or without food[1]

Tablet should be swallowed whole[1]

No titration needed[1]

Missed dose[1]

A missed dose should be taken right away. If it is almost time for the next dose, patients should be instructed to skip the missed dose and take the next dose as scheduled.

Usage and dose modifications

Dose modifications for drug interactions

CYP3A4 inhibitors[1]

Strong CYP3A4 inhibitors: AQUIPTA 60 mg is not suitable for these patients. The recommended dosage of AQUIPTA is 10 mg (10 mg presentation not available in NZ).

Moderate or weak CYP3A inhibitors: No dosage adjustment of AQUIPTA is needed.

OATP inhibitors[1]

AQUIPTA 60 mg is not suitable for these patients. The recommended dosage of AQUIPTA is 10 mg (10 mg presentation not available in NZ).

Use in specific populations

Use in hepatic impairment[1]

Severe hepatic impairment: Avoid use of AQUIPTA

Mild or moderate hepatic impairment: No dosage adjustment of AQUIPTA is needed.

Use in renal impairment[1]

Severe renal impairment (CrCl 15-29 mL/min), and end-stage renal disease (ESRD) (CrCl <15 mL/min): AQUIPTA 60 mg is not suitable for these patients. The recommended dosage of AQUIPTA is 10 mg (10 mg presentation not available in NZ).

For patients with ESRD undergoing intermittent dialysis, AQUIPTA should preferably be taken after dialysis.

Mild or moderate renal impairment: No dose adjustment is recommended.

Use in pregnancy – Pregnancy Category B3[1]

There are no data from the use of AQUIPTA in pregnant women. Studies in animals have shown reproductive toxicity. AQUIPTA is not recommended during pregnancy.

Use in lactation[1]

The cumulative amount of atogepant excreted in breast milk over 24 hours was minimal, at less than 0.01 mg. There are no data on the effects of atogepant on the breastfed infant, or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AQUIPTA and any potential adverse effects on the breastfed infant from AQUIPTA or from the underlying maternal condition.

Please refer to the full Data Sheet for details.

AQUIPTA®
(atogepant) tablets

How to access

AQUIPTA is now available in New Zealand for private purchase with a valid prescription.

Step 1: Patient visits GP or Specialist

1. GP or Specialist determines if patient is suitable for AQUIPTA.
2. Patient is willing to pay for private prescription.

Step 2: Prescription sent to pharmacy

To be eligible for the access program with the discounted price, the GP or Specialist will send the e-script to Airport Oaks Pharmacy.

Step 3: Patient receives medicine

1. Airport Oaks Pharmacy calls patient to arrange payment.
2. Patient either collects AQUIPTA from Airport Oaks Pharmacy or Airport Oaks Pharmacy will courier to the chosen address.

How does your patient access AQUIPTA?

AQUIPTA is available for private purchase in New Zealand with a valid prescription.

An access program has been established with Airport Oaks Pharmacy to make AQUIPTA available at a discounted price to patients. Airport Oaks Pharmacy can courier AQUIPTA anywhere in New Zealand. AbbVie reserves the right to cease providing the access program with reasonable notice being provided.

Outside of the access program, AQUIPTA is also available for private purchase with prescription from any other pharmacy. It is suggested your patient check the price with the selected pharmacy as prices may vary.

It is recommended that your patient check with their chosen pharmacy how many days to allow for AQUIPTA to arrive.

There are no cold chain storage requirements for AQUIPTA.

Only the 60 mg x 28 tablet bottle presentation is available in New Zealand. The recommended dose is one 60 mg tablet per day for most patients. Please refer to the AQUIPTA Data Sheet for dose modifications.

AQUIPTA is not currently funded by Pharmac. A funding application has been submitted to Pharmac, however there are no definite timelines on when or if a decision will be made by Pharmac to fund AQUIPTA.

What is the price of AQUIPTA?

As part of the access program, the maximum price charged to the patient for AQUIPTA from Airport Oaks Pharmacy will be NZ$352.82 (inclusive of GST) for 60 mg x 28 tablet pack (28 days supply).

If AQUIPTA needs to be couriered to the patient, Airport Oaks Pharmacy uses NZ Post as their courier. A standard metropolitan delivery fee of $5.75 will be charged in addition to the cost of AQUIPTA. If rural delivery is required, an additional $6.90 fee will also be charged on top of the standard metropolitan delivery fee. These courier prices are effective as of September 2024 but are subject to change based on NZ Post pricing.

Outside of the access program, AQUIPTA is also available for purchase with a prescription from any other pharmacy. It is suggested your patient check the price with the selected pharmacy before proceeding as prices may vary.

If your patient has health insurance that may cover the cost of medicines, it is recommended they discuss with their provider to determine if the cost of AQUIPTA would be covered under their policy.

Why is the access program only available at one pharmacy?

An access program has been established with Airport Oaks Pharmacy to make AQUIPTA available at a discounted price. Following a closed request for information process, Airport Oaks Pharmacy was selected as the most suitable pharmacy to participate in the access program. Airport Oaks Pharmacy can courier AQUIPTA anywhere in New Zealand.

The access program may be extended to other pharmacies, subject to them being able to meet certain criteria and signing up to the relevant terms and conditions for the access program. Please refer to the AbbVie Pro website abbv.ie/nz-aquipta-hcp for the most up to date information on pharmacies included in the access program. If a pharmacy wants to enquire about the access program, they should contact AbbVie on 0800 900 030.

What is the process for accessing AQUIPTA from Airport Oaks Pharmacy?

Send the e-script to Airport Oaks Pharmacy. Airport Oaks Pharmacy will call the patient to facilitate payment for AQUIPTA. There are several payment options available. Once payment is received, your patient can collect AQUIPTA from Airport Oaks Pharmacy or it can be couriered to their chosen address (at a standard rate set by NZ Post). It is recommended your patient check with Airport Oaks Pharmacy how many days it will take for AQUIPTA to arrive.

What is the process for accessing AQUIPTA at any other pharmacy?

Send the e-script to the selected pharmacy. Any pharmacy can order AQUIPTA as it does for any other medicine. It is suggested that the patient confirms with the selected pharmacy the cost of AQUIPTA and how long it will take to get the medicine before proceeding.

WHAT COULD YOUR PATIENTS DO WITH MORE MIGRAINE-FREE DAYS?^

^Across 12 weeks, patients experienced more migraine-free days with AQUIPTA 60 mg for both episodic and chronic migraine vs. placebo.*[1-3]

***Episodic migraine (OTHE population analysis):** Significant -4.1 (52.5%) mean migraine day reduction from 7.8 baseline (n=226) vs. -2.5 (33.3%) from 7.5 baseline for placebo (n=216; $p<0.001$).[1] **Chronic migraine (OTHE population analysis):** Significant -6.8 (35.4%) mean migraine day reduction from 19.2 baseline (n=257) vs. -5.1 (26.8%) from 19.0 for placebo (n=249; $p<0.002$).[1]

Study design

ADVANCE trial (Phase 2b/3 Dose-finding Study; Episodic migraine): Two randomised, double-blind, placebo-controlled, parallel-group studies that evaluated the efficacy and safety of AQUIPTA for 12 weeks in patients who were experiencing 4 to 14 migraine days per month. Patients had a mean age of 42 years (range: 18 to 73 years), 89% were female, and 83% were White. The studies excluded patients with myocardial infarction, stroke, or transient ischaemic attacks within 6 months prior to screening. Patients were allowed to use acute migraine medications (triptans, ergot derivatives, opioids, analgesic (including paracetamol), NSAIDs and antiemetic agents during the trial.[1,2]

The primary efficacy endpoint was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period. Additional endpoints included the change from baseline in mean monthly headache days, the change from baseline in mean monthly acute medication use days, the proportion of patients achieving at least a 50% and 75% reduction from baseline in mean MMD (3-month average), and change from baseline at week 12 for Headache Impact Test (HIT-6) total score and Migraine Specific Quality of Life Questionnaire version 2.1 (MSQ v2.1) Role Function-Restrictive (RFR) domain score.[1,2]

Open-label, Long-term Safety Study Design: A multicentre, randomised, open-label, 52-week long-term safety study to evaluate the safety and tolerability of AQUIPTA 60 mg in participants who experienced 4 to 14 migraine days per month. Participants were randomised to either AQUIPTA 60 mg once daily or oral standard-of-care migraine prevention medication. Efficacy variables for long-term efficacy evaluation were not classified as primary, secondary, or additional endpoints. Efficacy measures were only collected for the AQUIPTA group. Patients had a mean age was 42.5 years, 88.3% were female and 76.8% were White. Participants were excluded if they had difficulty distinguishing migraine from other tension-type headaches, had a current diagnosis of chronic migraine, or had experienced a mean of 15 or more headache days per month in the previous 3 months.[11]

PROGRESS trial (Phase 3 study; Chronic migraine): A randomised, double-blind, placebo-controlled, parallel-group study that evaluated the efficacy and safety of AQUIPTA for 12 weeks in patients for the prophylaxis of chronic migraine (15 or more headache days per month with at least 8 migraine days per month). Patients had a mean age of 42 years (range: 18 to 74 years), 87% were female, 60% were White and 36% Asian. A subset of patients (11%) was allowed to use one concomitant migraine prophylaxis medication (e.g., amitriptyline, propranolol, topiramate). Patients were allowed to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, paracetamol and opioids) as needed. The study excluded patients with myocardial infarction, stroke, or transient ischaemic attacks within 6 months prior to screening.[1,3]

The primary efficacy endpoint was the change from baseline in mean MMD across the 12-week treatment period. Additional endpoints included the change from baseline in mean monthly headache days, the change from baseline in mean monthly acute medication use days, the proportion of patients achieving at least a 50% and 75% reduction from baseline in mean MMD (3-month average), and change from baseline at week 12 for HIT-6 total score and MSQ v2.1 RFR domain score.[1,3]

Analysis method

OTHE population analysis: Both on-treatment and off-treatment data were considered in the efficacy analysis done in the off-treatment hypothetical estimand (OTHE) population, which included all randomly assigned participants who received at least one dose of study intervention, had an evaluable baseline period of eDiary data, and at least one evaluable post-baseline 4-week period (weeks 1–4, 5–8, and 9–12) of eDiary data during the study, regardless of whether on or off study treatment.[3]

AQUIPTA®
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Minimum Data Sheet – AQUIPTA tablets

AQUIPTA is an unfunded Prescription Medicine - charges will apply.

Please review full Data Sheet before prescribing. This is available on request from AbbVie Limited by calling 0800 900 030 or at abbv.ie/nz-aqui-ds.

Indications

AQUIPTA is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

Contraindications

History of hypersensitivity to atogepant or any components of AQUIPTA. Reactions have included anaphylaxis and dyspnoea.

Precautions

Hypersensitivity reactions, including anaphylaxis, dyspnoea, rash, pruritus, urticaria, and facial oedema have been reported with use of AQUIPTA. Some hypersensitivity reactions can occur days after administration. If hypersensitivity reaction occurs, discontinue AQUIPTA and institute appropriate therapy. Not recommended in patients with severe hepatic impairment; not recommended in pregnancy; lactation; sodium content; severe renal impairment or end-stage renal disease; safety and efficacy of AQUIPTA in paediatric population have not been established. See Data Sheet for details.

Interactions

Potential for significant drug interactions requiring AQUIPTA dose adjustment when administered concomitantly with strong CYP3A4 inhibitors and inducers and strong OATP inhibitors, e.g., ketoconazole, itraconazole, clarithromycin, cyclosporine, rifampicin. See Data Sheet for details (not all AQUIPTA presentations may be marketed).

Adverse effects

Nausea, constipation, fatigue/somnolence, decreased appetite, hypersensitivity (e.g., anaphylaxis, dyspnoea, rash, pruritus, urticaria, facial oedema). See Data Sheet for additional information on adverse effects.

Dosage and administration

The recommended oral dosage of AQUIPTA is one atogepant 60 mg tablet once daily with or without food. See Data Sheet for additional information on dose modification.

Version 1

Abbreviations: CGRP, calcitonin gene-related peptide; **CrCl,** creatinine clearance; **CYP3A4,** Cytochrome P450 3A4; **ESRD,** end-stage renal disease; **HIT-6,** Headache Impact Test total score; **mITT,** modified intention-to-treat; **MMD,** monthly migraine days; **MSQv2.1,** Migraine Specific Quality of Life Questionnaire version 2.1; **NSAIDs,** nonsteroidal anti-inflammatory drugs; **RFR,** Role Function-Restrictive domain score; **OATP,** organic anion transporting polypeptide; **OTHE,** off-treatment hypothetical estimand; **QD,** once daily; **TEAE,** treatment emergent adverse event.

References: 1. AQUIPTA (atogepant) Data Sheet. **2.** Ailani J, *et al. N Engl J Med.* 2021;385(8):695-706. **3.** Pozo-Rosich P, *et al. Lancet.* 2023, 402:775-85. **4.** Global Burden of Disease Study 2016. *Lancet Neurol.* 2018;17:954–976. **5.** Martelletti P, *et al. J Headache Pain.* 2018;19(1):115. **6.** Migraine Foundation Aotearoa New Zealand. Migraine in NZ. Accessed at: migrainefoundation.org.nz/migraine-in-nz/ (April 2025). **7.** Russo AF. *Annu Rev Pharmacol Toxicol.* 2015;55:533-552. **8.** Edvinsson L, *et al. Nat Rev Neurol.* 2018;14(6):338-350. **9.** Edvinsson L. *Headache.* 2017;57(suppl 2):47-55. **10.** Schwedt TJ, *et al. Cephalalgia.* 2022;42(1):3-11. **11.** Ashina M, *et al. Headache.* 2023;63(1):79-88. **12.** AbbVie data on file ABVRRTI78008.

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Contact us
AbbVie Limited
Telephone: 0800 900 030

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