Aqvesme™ (mitapivat) tablets 100mg

myagios®

Helping navigate the path ahead

All-in-one enrollment and support for your patients

myAgios® Patient Support Services offers a single point of engagement for you and your office staff when seeking care for your patients living with thalassemia. AQVESME™ has a Risk Evaluation and Mitigation Strategy (REMS) to help ensure safe use, regulatory compliance, and coordinated care for patients.

Personalized Patient Education

Every patient's treatment experience is unique. Our Agios Clinical Educators (ACEs) will share information that is tailored to each patient's individual needs, providing education and support pre- and post-prescription.

Support Through Enrollment

A one-time AQVESME REMS certification is required for prescribers (AQVESMEREMS.com).

Before treatment initiation:

1. Counsel the patient
2. Obtain patient's pre-treatment liver test
3. Complete 2 forms

Access and Assistance

Patient Support Managers (PSMs) partner with your patients and your practice to facilitate access to AQVESME. They will help coordinate insurance and delivery through the exclusive REMS-certified Specialty Pharmacy.

Customized Treatment Support and Adherence

Through their ACE or PSM, patients can get help preparing for appointments, receive friendly reminders for monthly liver monitoring, and have their questions about AQVESME answered by text or phone.

ACEs and PSMs do not provide medical advice. For medical advice or treatment-related questions, patients are instructed to talk to their healthcare team.

For any questions regarding REMS, visit **www.AQVESMEREMS.com** or call **1-800-625-9951**

INDICATION

AQVESME is indicated for the treatment of anemia in adults with alpha- or beta-thalassemia.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HEPATOCELLULAR INJURY

AQVESME can cause serious hepatocellular injury. Measure liver laboratory tests (ALT, AST, alkaline phosphatase and total bilirubin with fractionation) at baseline and every 4 weeks for 24 weeks and then as clinically indicated. Avoid use of AQVESME in patients with cirrhosis. Discontinue AQVESME if hepatic injury is suspected.
Because of the risk of hepatocellular injury, AQVESME is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AQVESME REMS.

Please see additional Important Safety Information throughout and full Prescribing Information for AQVESME, including Boxed Warning.

Monthly support for your patients and your practice

Month 0-1

Onboarding and Education

myAgios® Patient Support Services will welcome your patient to the program by providing product education and next steps on how to access AQVESME™ (mitapivat).

Month 1-2

Initial Monitoring and Rapport Building

myAgios will educate the patient on ongoing liver tests and identify treatment goals.

Month 2-3

Addressing Barriers and Motivation

Provide tailored support to identify challenges, facilitate solutions, and foster engagement.

Month 4

Ongoing Adherence and Check-In

myAgios will remind patients of the importance of taking AQVESME as prescribed with the support of check in calls and refill reminders.

Month 5

Empowerment and Self-Management

Continue education, self-monitoring and check in on treatment goals.

Month 6

Sustainability

Solidify habits, prepare for ongoing maintenance, and discuss any changes to insurance.

We help your patients start and stay on AQVESME

Your dedicated myAgios team:

Builds Strong Patient Connections

We maintain regular outreach to provide education, encouragement, and support throughout the treatment journey.

Identifies Adherence Risks Early

We use simple assessment tools to spot potential barriers and reinforce behaviors that help keep patients on therapy.

Increases Engagement Between Visits

We share timely digital content and reminders to help patients stay motivated and aligned with their treatment plan.

Helps Patients Establish Consistent Routines

We encourage monitoring symptoms, dose tracking, and healthy habits that strengthen long-term adherence.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS

Hepatocellular Injury

AQVESME can cause hepatocellular injury. Avoid use of AQVESME in patients with cirrhosis. In patients with thalassemia treated with AQVESME, liver injury with and without jaundice has been observed within the first 6 months of exposure. Obtain liver tests (including ALT, AST, alkaline phosphatase, total bilirubin with fractionation) prior to the initiation of AQVESME, then every 4 weeks for the first 24 weeks, and as clinically indicated thereafter. Interrupt AQVESME if clinically significant increases in liver tests are observed or alanine aminotransferase is >5 times the upper limit of normal (ULN). Complete a comprehensive evaluation to rule out other causes of liver injury when drug-induced liver injury is suspected. Discontinue AQVESME if hepatocellular injury due to AQVESME is suspected.

Please see additional Important Safety Information throughout and full Prescribing Information for AQVESME, including Boxed Warning.

Your patients have a dedicated team at myAgios® Patient Support Services

Agios Clinical Educators (ACEs) and Patient Support Managers (PSMs) are here to help guide your patients living with thalassemia along every step of their journey.

What's an ACE?

An ACE is there from the start to offer personalized guidance to people living with thalassemia with or without a prescription.

ACEs help your patients:

- Get introduced to the PSM to learn more about their health insurance options
- Learn about their disease
- Set goals for living with their condition and discuss treatment and monitoring considerations
- Connect with other patients and hear from experts on webinars

What's a PSM?

A PSM helps people prescribed AQVESME™ (mitapivat) get access to and stay on AQVESME.

PSMs help your patients:

- Connect to ACEs to learn about their condition and treatment considerations
- Understand financial assistance and any eligibility criteria
- Get their AQVESME prescription filled
- Provide support through ongoing adherence

PSMs help you and your office:

- Navigate the patient's insurance coverage
- Address prior authorization requirements and appeals
- Coordinate all fulfillment and delivery with the exclusive Specialty Pharmacy

The myAgios team can connect with your patients in their preferred language, including Chinese, Arabic, Vietnamese, and others.

ACEs and PSMs do not provide medical advice. For medical advice or treatment-related questions, patients are instructed to talk to their healthcare team.

IMPORTANT SAFETY INFORMATION (cont.)

Hepatocellular Injury (cont.)

Symptoms and signs of early liver injury may mimic those of thalassemia. Advise patients to report new or worsening symptoms of loss of appetite, nausea, right-upper-quadrant abdominal pain, vomiting, scleral icterus, jaundice, or dark urine while on AQVESME treatment.

During the double-blind period, 2 of 301 patients (0.66%) with thalassemia treated with AQVESME experienced adverse reactions suggestive of hepatocellular injury. Three additional patients experienced adverse reactions suggestive of hepatocellular injury during the open-label extension periods after switching from placebo to AQVESME. Of these 5 patients, 2 had serious liver injury requiring hospitalization, including 1 patient who developed jaundice (peak bilirubin 32 mg/dL). Another patient developed jaundice (peak bilirubin 4 mg/dL) without requiring hospitalization. These reactions were characterized by a time to onset within the first 6 months of treatment with peak elevations of alanine aminotransferase of >5×ULN with or without jaundice. All patients discontinued treatment with AQVESME, and these reactions improved upon treatment discontinuation.

AQVESME REMS

AQVESME is available only through a restricted program under a REMS called the AQVESME REMS because of the risk of hepatocellular injury.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) among patients taking AQVESME were headache and insomnia.

Please see additional Important Safety Information throughout and full Prescribing Information for AQVESME, including Boxed Warning.

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Start AQVESME™ in 3 simple steps

Once you and your patient have reviewed AQVESME clinical and REMS information and decided AQVESME is right for them, these are the steps to start treatment promptly:

1

Complete the AQVESME Start Form and your one-time HCP AQVESME REMS certification

After you and your patient sign and submit the AQVESME Start Form, the patient will be enrolled in myAgios® Patient Support Services. The myAgios team can assist you and your patient in determining insurance coverage and exploring financial assistance options.

2

Ensure your patient's pre-treatment liver test is completed

The pre-treatment liver test (blood test) must be completed within 4 weeks of the first prescription being filled. The myAgios team will work with you and your patient to determine the ideal timing to complete the required pre-treatment liver test based on the status of insurance determination.

3

Enroll your patient in AQVESME REMS

To enroll, you and your patient must complete and sign the AQVESME REMS Patient Enrollment Form, including documentation of the patient's pre-treatment liver test and confirmation that the patient is appropriate for AQVESME.

The myAgios team will help ensure AQVESME is delivered directly to your patient's home through an exclusive REMS-certified Specialty Pharmacy.

Scan to prescribe AQVESME and connect your patient to myAgios.
Visit myagios.com/aqvesme/hcp for the AQVESME Start Form and more.

For any questions regarding REMS, visit **www.AQVESMEREMS.com** or call **1-800-625-9951**.

For any questions regarding myAgios, visit **myAgios.com** or call **1-877-77-AGIOS** (1-877-772-4467).

IMPORTANT SAFETY INFORMATION (cont.)

DRUG INTERACTIONS

- Strong CYP3A Inhibitors and Inducers: Avoid concomitant use.
- Moderate CYP3A Inhibitors: Avoid concomitant use.
- Moderate CYP3A Inducers: Consider alternatives that are not moderate inducers. If there are no alternatives, see full Prescribing Information for recommended dosage for drug interactions with moderate CYP3A inducers.
- Sensitive CYP3A Substrates, including hormonal contraceptives: Avoid concomitant use with substrates that have narrow therapeutic index.
- CYP2B6, CYP2C, and UGT1A1 Substrates: Monitor patients for efficacy of the substrates with narrow therapeutic index.
- P-gp Substrates: Monitor patients for adverse reactions of the substrates with narrow therapeutic index.

HEPATIC IMPAIRMENT

Avoid use of AQVESME in patients with cirrhosis (Child-Pugh Class A, B, or C).

Please see full Prescribing Information for AQVESME, including Boxed Warning.

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