MEDICATION GUIDE
AQVESME (ak ves' mee)
(mitapivat)
tablets, for oral use

What is the most important information I should know about AQVESME?
AQVESME can cause serious side effects, including:

- **Liver injury**. AQVESME can cause serious liver injury. Liver injury has happened in people with thalassemia within the first 6 months of treatment with AQVESME. Your healthcare provider will do blood tests to check your liver before you start treatment with AQVESME, every 4 weeks for the first 24 weeks of treatment, and as needed. Your healthcare provider may temporarily or permanently stop your treatment with AQVESME if you have abnormal liver blood tests. Tell your healthcare provider right away if you develop any new or worsening signs or symptoms of liver problems including:
  - loss of appetite
  - nausea
  - pain in the upper right side of your stomach area
  - vomiting
  - yellowing of the skin or white part of your eyes (jaundice)
  - dark-colored urine
- **Because of the risk of liver injury, AQVESME is only available through a restricted program called the AQVESME Risk Evaluation and Mitigation Strategy (REMS)**.
  - Your healthcare provider must be enrolled in the AQVESME REMS for you to be prescribed AQVESME.
  - Before you start treatment with AQVESME, you must enroll in the AQVESME REMS. Talk to your healthcare provider about how to enroll in the AQVESME REMS.
  - Before you take AQVESME, your healthcare provider will make sure you understand how to take AQVESME safely, which will include liver tests when advised by your healthcare provider. Your healthcare provider will counsel you on the risk of liver injury and the REMS requirements.
  - AQVESME can only be dispensed by a certified pharmacy that participates in the AQVESME REMS. Your healthcare provider can give you information on how to find a certified pharmacy.
  - If you have any questions about the AQVESME REMS, ask your healthcare provider, go to www.aqvesmerems.com or call 1-800-625-9951.

See "What are the possible side effects of AQVESME?" for more information about side effects.

What is AQVESME?
AQVESME is a prescription medicine used to treat anemia (low red blood cells) in adults with alpha- or beta-thalassemia.
It is not known if AQVESME is safe and effective in children.

Before taking AQVESME, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems, such as cirrhosis.
- are pregnant or plan to become pregnant. It is not known if AQVESME will harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with AQVESME.
- are breastfeeding or plan to breastfeed. It is not known if AQVESME passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with AQVESME.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Make sure to tell your healthcare provider if you take or use hormonal birth control (contraceptives). If you take or use hormonal birth control (except for intrauterine systems containing levonorgestrel), it may not work as well during treatment with AQVESME. Use a different type of birth control or use an additional nonhormonal birth control method (such as condoms) during treatment with AQVESME and for 28 days after stopping treatment with AQVESME.
- AQVESME and certain other medicines may affect each other and cause side effects.
- AQVESME may affect the way other medicines work, and other medicines may affect how AQVESME works.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take AQVESME?

- Take AQVESME exactly as your healthcare provider tells you to take it.
- Take AQVESME with or without food.

- Swallow AQVESME tablets whole. Do not split, crush, chew, or dissolve the tablets.
- If you miss a dose of AQVESME by 4 hours or less, take your dose as soon as possible. If more than 4 hours have passed since your regularly scheduled dose, do not take the missed dose and wait for the next dose. Return to your normal schedule at the next dose.

What are the possible side effects of AQVESME?

AQVESME can cause serious side effects:

- See "**What is the most important information I should know about AQVESME?**"

The most common side effects of AQVESME include headache and trouble sleeping (insomnia).

These are not all of the possible side effects of AQVESME.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AQVESME?

- Store AQVESME in a refrigerator between 36°F to 46°F (2°C to 8°C).
- You may also store AQVESME at room temperature between 68°F to 77°F (20°C to 25°C) for up to 3 months. If you remove AQVESME from the refrigerator, store AQVESME at room temperature.
  - Write the discard (throw away) date in the space provided on the blister wallet and the carton. The discard date is 3 months after you remove the tablets from the refrigerator.
  - Throw away AQVESME if not used by the written discard date or by the expiration date, whichever happens first.
- Store the blister wallets in the original carton until use.

Keep AQVESME and all medicines out of the reach of children.

General information about the safe and effective use of AQVESME.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AQVESME for a condition for which it was not prescribed. Do not give AQVESME to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AQVESME that is written for health professionals.

What are the ingredients in AQVESME?

Active ingredients: mitapivat

Inactive ingredients: croscarmellose sodium, mannitol, microcrystalline cellulose, and sodium stearyl fumarate.
The tablet film-coating contains: FD&C Blue No. 2, hypromellose, lactose monohydrate, titanium dioxide, triacetin, and macrogol/PEG.
The tablet printed with blue ink contains: ammonium hydroxide, FD&C Blue No. 1, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac glaze, and titanium dioxide.

Manufactured for and Distributed by: Agios Pharmaceuticals, Inc., Cambridge, MA 02139

For more information, visit www.aqvesme.com or call 1-833-228-8474.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 12/2025