

A guide to talking to your doctor about AQVESME

If you are living with **non-transfusion-dependent (NTD) thalassemia**

If you're living with transfusion-dependent thalassemia, see reverse side.



Use this guide to help start a conversation with your doctor about AQVESME.

Before your appointment

Write responses to these prompts and consider discussing them with your doctor. If you don't have the necessary information to write a response, verify it with your doctor.

1. My thalassemia symptoms include: For example, "fatigue," "weakness."

2. How thalassemia affects me: For example, "I am too tired to do things I'd like to do" or "I struggle to finish things because I'm tired."

3. New symptoms or symptoms that seem to be worsening:

4. My hemoglobin levels over time:

Most recent level: ____ g/dL on ____ / ____ / ____

Previous levels: ____ g/dL on ____ / ____ / ____, ____ g/dL on ____ / ____ / ____, ____ g/dL on ____ / ____ / ____

At your appointment

Use these questions to discuss AQVESME with your doctor.

Is AQVESME right for me? _____

How does AQVESME work? _____

How do I take AQVESME? _____

What are the potential benefits of AQVESME? _____

What are the possible side effects of AQVESME? _____

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.

IMPORTANT SAFETY INFORMATION

AQVESME may 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:

- o loss of appetite
- o nausea
- o pain in the upper right side of your stomach area
- o vomiting
- o yellowing of the skin and white part of your eyes (jaundice)
- o dark-colored urine

In clinical studies of AQVESME, 2 of 301 people (0.66%) treated with AQVESME experienced adverse reactions suggestive of liver injury. Three additional people experienced adverse reactions suggestive of liver injury during the open-label extension periods, after switching from placebo to AQVESME. Of the 5 people, two had serious liver injury requiring hospitalization, including 1 who developed jaundice. Another developed jaundice without requiring hospitalization. All 5 people discontinued treatment with AQVESME, and these reactions improved upon treatment discontinuation.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

A guide to talking to your doctor about AQVESME



If you are living with **transfusion-dependent (TD) thalassemia**

If you're living with non-transfusion-dependent thalassemia, see reverse side.

Use this guide to help start a conversation with your doctor about AQVESME.

Before your appointment

Write responses to these prompts and consider discussing them with your doctor. If you don't have the necessary information to write a response, verify it with your doctor.

1. My transfusion schedule:

I get a transfusion every ____ (weeks/months) of ____ red blood cell units.

2. Time spent on transfusions:

Each one usually takes ____ hours.

3. How my transfusions have changed over time: For example, "I need more red blood cell units per transfusion."

4. My treatment goal: For example, "My goal is to reduce my transfusion frequency."

At your appointment

Use these questions to discuss AQVESME with your doctor.

Is AQVESME right for me? _____

How does AQVESME work? _____

How do I take AQVESME? _____

What are the potential benefits of AQVESME? _____

What are the possible side effects of AQVESME? _____

IMPORTANT SAFETY INFORMATION (cont.)

Because of the risk for liver injury, AQVESME is only available through a restricted access program called the AQVESME Risk Evaluation and Mitigation Strategy (REMS).

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 the way AQVESME works.

The most common side effects of AQVESME in patients:

- headache
- 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](https://www.fda.gov/medwatch).

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide