

Frequently Asked Questions

AUVI-Q Availability

What is AUVI-Q?

AUVI-Q is an FDA-approved prescription medicine used to treat life-threatening allergic reactions, including anaphylaxis, in people who are at risk for or have a history of serious allergic reactions. It is a compact epinephrine auto-injector with innovative features such as voice instructions that help guide a user with step-by-step instructions through the epinephrine delivery process and is the first-and-only epinephrine auto-injector with an auto-retractable needle. Please visit www.auvi-q.com for a complete product description.

What is the “AUVI-Q AffordAbility™” program?

AUVI-Q AffordAbility is a first-of-its-kind access program for AUVI-Q. To learn more about the program as well as our pricing philosophy, visit www.auvi-q.com/AffordAbility.

How much will patients have to pay out-of-pocket for AUVI-Q?

Through this new program, more than 200 million Americans with commercial insurance, including those with high deductible plans, will be able to obtain AUVI-Q for a \$0 out-of-pocket cost. For eligible patients who do not have government or commercial insurance, and have a household income of less than \$100,000, AUVI-Q will be available free of charge.

If a patient has a Medicare or Medicaid plan, will AUVI-Q be covered?

Some Medicare and Medicaid plans will provide coverage for AUVI-Q; however, coverage for those patients with government-sponsored health plans may vary widely. Patients should contact their government insurance provider for the most up-to-date information regarding AUVI-Q coverage.

When will AUVI-Q be available for prescription?

AUVI-Q will be available for prescription in the United States on February 14, 2017. AUVI-Q will also be available via a direct delivery service to a physician's office or a patient's home within 48 hours in most cases. The direct delivery service option helps ensure the best expiration dating for AUVI-Q. For general questions or live assistance in filling an AUVI-Q prescription, any patient, physician, or pharmacist can call the hotline at 1-877-30-AUVIQ.

What is the shelf life of AUVI-Q?

Our goal is to provide patients with at least 12 months of expiration dating when they receive the AUVI-Q from the pharmacy. A benefit of using the direct delivery service is to help guarantee the best expiration dating for AUVI-Q.

How is AUVI-Q made?

AUVI-Q is manufactured with an intelligent, high-tech, 100% automated robotic production line with over 100 automated quality checks on each AUVI-Q device, ensuring a streamlined and consistent production process. Kaléo uses specially calibrated sensors and vision inspection systems to help ensure each component is assembled into AUVI-Q with precision.

Indication

AUVI-Q® (epinephrine injection, USP) is a prescription medicine used to treat life-threatening allergic reactions, including anaphylaxis, in people who are at risk for or have a history of serious allergic reactions.

Important Safety Information

AUVI-Q is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use. Each AUVI-Q contains a single dose of epinephrine. **AUVI-Q should only be injected into your outer thigh, through clothing if necessary.** If you inject a young child with AUVI-Q, hold their leg firmly in place before and during the injection to prevent injuries. Do not inject into veins, buttocks, fingers, toes, hands, or feet. If you accidentally inject AUVI-Q into any other part of your body, seek immediate medical treatment.

Rarely, patients who use AUVI-Q may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following symptoms at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have more or longer lasting side effects when you use AUVI-Q. Be sure to tell your healthcare provider about all the medicines you take, especially medicines for asthma. Also tell your healthcare provider about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, heart problems or high blood pressure, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Common side effects include fast, irregular or 'pounding' heartbeat, sweating, shakiness, headache, paleness, feelings of over excitement, nervousness, or anxiety, weakness, dizziness, nausea and vomiting, or breathing problems. These side effects usually go away quickly, especially if you rest. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Please see the full Prescribing Information and the Patient Information at www.auvi-q.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.