



AUVI-Q® EPINEPHRINE INJECTION, USP

MANUFACTURING REPORT



“At kaléo, we hold ourselves accountable to building quality systematically into our products. We are committed to continually testing and improving AUVI-Q to help patients and their caregivers to confidently administer epinephrine in life-threatening allergic emergencies.”

Ann Rademacher,

Vice President, Quality Assurance, kaléo

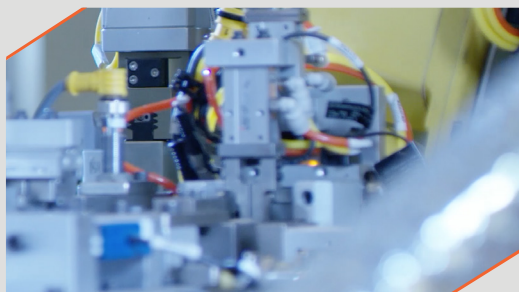
INDICATION

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.

MANUFACTURING EXCELLENCE



We perform critical device functionality quality tests throughout the production process, selecting and activating AUVI-Qs during each run. This means that during production, we can ensure the manufacturing process is tightly controlled.

- » **Kaléo** is a pharmaceutical company that develops new generation lifesaving personal medical products, including AUVI-Q which helps patients and their caregivers to confidently administer epinephrine in life-threatening allergic emergencies.
- » **AUVI-Q** was developed by patients with life-threatening allergies, for patients with life-threatening allergies. AUVI-Q is the only epinephrine auto-injector that is the size of a credit card and the thickness of a cellphone. It's easy to carry with industry-first features including:
 - A voice prompt system that guides a user with step-by-step instructions through the delivery process
 - A needle that automatically retracts up into the housing so that the user never sees the needle before, during or after administration
- » **For more** information about AUVI-Q talk to your healthcare provider.
- » **Kaléo uses specially calibrated sensors** and vision inspection systems to ensure each component is assembled into AUVI-Q with precision.
- » **Every component** built into each AUVI-Q has an identifier and is tracked throughout the manufacturing process. If there are any component issues identified during production, the component is automatically rejected and immediately removed from the manufacturing process.
- » **AUVI-Q** is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Patients should seek immediate medical attention after administration of AUVI-Q.

ENSURING A STREAMLINED AND CONSISTENT PRODUCTION PROCESS FOR AUVI-Q MANUFACTURING:



An intelligent **HIGH-TECH, 100% AUTOMATED** robotic production line



OVER 100 AUTOMATED QUALITY CHECKS on each AUVI-Q

IMPORTANT SAFETY INFORMATION (CONTINUED)

Each AUVI-Q contains a single dose of epinephrine. AUVI-Q should only be injected into your outer thigh, through clothing if necessary.

MANUFACTURING EXCELLENCE (CONT'D)



21 ROBOTS with
more than **20 VISUAL**
CHECKS during the
assembly of AUVI-Q



ASSEMBLED here in
the **UNITED STATES**

-) **Kaléo strives for flawless manufacturing** to ensure each AUVI-Q device is built to exceptional quality standards
-) **AUVI-Q device manufacturing** is a seamless integration of state-of-the-art technology and manufacturing process design, happening right here in the United States.
-) **Human Factors Engineering (HFE)** has been central to kaléo's development approach from the very beginning. HFE puts the patient and caregivers, such as family members, at the center of our development process in order to design products that are easy to operate and, most importantly, support correct and safe use. One of our goals is to help remove the potential for error when using AUVI-Q during life-threatening allergic emergencies.

AUVI-Q includes a voice prompt system that guides a user with step-by-step instructions through the delivery process, and has a needle that automatically retracts following administration.

AUVI-Q is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Patients should seek immediate medical attention after administration of AUVI-Q.

"Since the time we were young teenagers, we wanted to create an innovative epinephrine auto-injector. As patients and parents of children with life-threatening allergies, we know how the moment of an allergic emergency can unfold – with panic and fear – and that's why we believe and trust in AUVI-Q not only for ourselves but for our children and other families, who may have to depend upon it."

– Evan Edwards,

Vice President, Product Development and Industrialization



"As VP of Quality Assurance at kaléo, I am responsible for establishing and maintaining the quality systems for the development and production of our products including AUVI-Q. We're always looking for ways to advance our manufacturing processes and continually striving for the highest possible quality of our products.

We understand that you and your loved ones count on the safety and reliability of your epinephrine auto-injectors, as do our own families."

– Ann Rademacher,

Vice President, Quality Assurance

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

FREQUENTLY ASKED QUESTIONS

FREQUENTLY ASKED QUESTIONS ABOUT THE VOLUNTARY RECALL OF AUVI-Q IN 2015

Q: When did kaléo regain the rights to AUVI-Q?

A: Effective February 2016, kaléo regained all rights to AUVI-Q, including research and development, manufacturing and commercialization rights.

Q: Has kaléo addressed the cause of the voluntary recall?

A: Kaléo has identified and resolved the issue that led to the 2015 recall of AUVI-Q. Kaléo also conducted a thorough risk analysis of each assembly station on the AUVI-Q manufacturing line and has invested in manufacturing updates, new quality inspections and continuous manufacturing improvement initiatives to help ensure an issue like this will not happen in the future.

Q: What processes are in place to ensure this doesn't happen again?

A: AUVI-Q is manufactured on 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's automated robotic production line helps us produce a consistent, high-quality product.

Kaléo uses specially calibrated sensors and vision inspection systems to ensure each component is assembled into AUVI-Q with precision. Every component built into each AUVI-Q has an identifier and is tracked throughout the manufacturing process. To learn more about our state-of-the-art technology, manufacturing processes and quality controls, please watch this [video](#).

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.