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 using AUVI-Q. 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 or infant with AUVI-Q, hold their leg firmly in place before and during the injection to prevent injuries. Do not inject AUVI-Q into any other part of your body, such as into veins, buttocks, fingers, toes, hands, or feet. If this occurs, seek immediate medical treatment and make sure to inform the healthcare provider of the location of the accidental injection. Only a healthcare provider should give additional doses of epinephrine if more than two doses are necessary for a single allergic emergency.

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 <u>Prescribing Information</u> and the <u>Patient Information</u>.

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.