

Auvi-Q[®] (epinephrine) – Expanded indication

- On November 20, 2017, [Kaleo announced](#) the [FDA approval](#) of [Auvi-Q \(epinephrine\)](#) injection for emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (eg, order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (eg, triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (eg, radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis in patients weighing 7.5 to 15 kg (16.5 to 33 lbs).
 - Previously, Auvi-Q was only approved for use in patients weighing ≥ 15 kg (≥ 33 lbs).
 - Auvi-Q is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.
 - Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.
- The expanded indication is supported by the approval of a 0.1 mg/0.1mL Auvi-Q auto-injector. The 0.1 mg dose has a shorter needle length and lower dose of epinephrine than the current FDA approved 0.15 mg and 0.3 mg Auvi-Q auto-injectors.
- Auvi-Q is the only compact epinephrine auto-injector with a voice instruction system that helps guide patients and caregivers step-by-step through the injection process, and a needle that automatically retracts following administration.
 - Epinephrine injection is also available as [EpiPen[®]](#), EpiPen Jr[®], [Adrenalin[®]](#), [Adrenaclick[®]](#), and various generic products (vials, ampules, and prefilled syringes).
 - The EpiPen and Adrenaclick 0.3 mg auto-injectors and Adrenalin vials may be used in patients weighing ≥ 30 kg (66 lbs). EpiPen Jr and Adrenaclick 0.15 mg auto-injectors may be used in patients weighing 15 to 30 kg (33 to 66 lbs). Adrenalin vials may also be used in patients weighing ≤ 30 kg.
 - Refer to individual prescribing labels for more information. These products are not therapeutically equivalent to each other.
- Auvi-Q is injected intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Selection of the appropriate Auvi-Q strength is determined according to the patient's body weight:
 - Weight ≥ 30 kg (≥ 66 lbs): Auvi-Q 0.3 mg
 - Weight 15 to 30 kg (33 to 66 lbs): Auvi-Q 0.15 mg
 - Weight 7.5 to 15 kg (16.5 to 33 lbs): Auvi-Q 0.1 mg
- Each Auvi-Q contains a single dose of epinephrine for single-use injection. Since the doses of epinephrine delivered from Auvi-Q are fixed, other forms of injectable epinephrine should be considered if a dose lower than 0.1 mg is deemed necessary.
- The wholesale acquisition cost of Auvi-Q is \$4,500 per carton of two pens.
- Kaleo plans to launch the Auvi-Q 0.1 mg auto-injector in the first half of 2018.