News Articles, FDA Update, Allergy/Immunology

FDA approves epinephrine auto-injector for infants, toddlers

by from the Food and Drug Administration's Division of Pulmonary, Allergy and Rheumatology Products, Office of Pediatric Therapeutics, and Division of Pediatric and Maternal Health

The Food and Drug Administration (FDA) has approved a new lower dose epinephrine auto-injector for the emergency treatment of allergic reactions in infants and toddlers.

Auvi-Q (epinephrine injection) now comes in 0.1 milligram (mg) strength for patients who weigh 7.5 to 15 kilograms (kg) (16.5 to 33 pounds). Epinephrine auto-injectors previously were available in two strengths: 0.15 mg for patients weighing 15 to 30 kg (33 to 66 pounds) and 0.3 mg for patients at least 30 kg (66 pounds).

New labeling approved on Nov. 17 also shortens the time that this lower dose auto-injector must be held in place against the thigh from five seconds to two seconds after activation.

Use of epinephrine should not be delayed in an allergic emergency, including anaphylaxis. Immediate medical or hospital care should be sought along with epinephrine administration.

Auvi-Q facts:

- Auvi-Q should be injected into the anterolateral aspect of the thigh, through clothing if necessary.
- Since infants and young children may kick or move during an injection, parents and caregivers should be instructed to hold the leg firmly in place and limit movement prior to and during injection.
- Each dosage strength is available in a different color scheme: 0.1 mg (lavender), 0.15 mg (blue) and 0.3 mg (red).
- Each carton contains two devices, a trainer that does not contain a needle or medicine, patient information and instructions for use.
- Each device is a single-use injection.
- Products include both auditory and visual cues to help patients and caregivers administer the product appropriately.
- Patients and caregivers should be instructed to review the injector's instructional and safety systems in advance.

Resources

- Product labeling for Auvi-Q
- Additional AAP News FDA Update columns