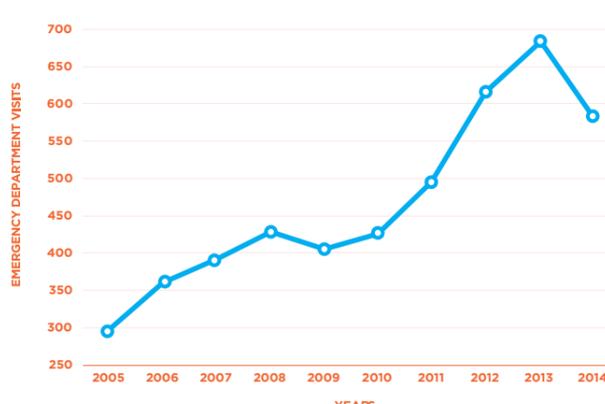


Unmet Medical Need in the Emergency Treatment of Life-Threatening Allergic Reactions

Food Allergy Stats and Figures

- According to the Centers for Disease Control & Prevention (CDC) between 1997-1999 and 2009- 2011, **food allergy prevalence among children aged 0-17 years increased by 50 percent.**¹
- Researchers now estimate that 1 in 13 children (8 percent) have food allergies.²
- Cow's milk, peanut and egg are typical food allergens for children aged 0-2 years.³

Emergency Department Visits for Anaphylaxis Among Children Four Years Old and Younger Increased by 129.8 Percent.⁴



Recognizing Anaphylactic Reactions in Infants and Toddlers Weighing 16.5 to 33 lbs (7.5 to 15 kg)

Anaphylaxis is a medical emergency and requires immediate treatment; however, diagnosis of anaphylaxis in infants and toddlers can be difficult.

- Many of the signs and symptoms of anaphylaxis in infants (e.g., vomiting, drooling, drowsiness) are subtle and may be mistaken as signs of normal development or other illnesses in infants.⁵
- Infants aged 13 months or younger may not be able to verbalize their symptoms.⁶
- The most common symptoms of anaphylaxis are hives, nausea/vomiting, and swelling for infants under the age of 2, and hives, swelling, and wheezing for toddlers aged 2-5.⁷

Epinephrine auto-injectors (EAI) represent the standard of care for the treatment of anaphylaxis in the out-of-the-hospital setting⁸, yet until now there has been no FDA-approved epinephrine auto-injector (EAI) for the treatment of children weighing 16.5 to 33 lbs (7.5 to 15 kg).

FDA-approved AUVI-q 0.1 mg is the first and only EAI specifically designed for the treatment of life-threatening allergic reactions, including anaphylaxis, in infants and toddlers weighing 16.5 to 33 lbs (7.5 to 15 kg) who are at risk for or have a history of serious allergic reactions.

The AUVI-q 0.1 mg auto-injector offers a lower dose of epinephrine and a shorter exposed needle length (approximately 7.4 mm) than current FDA-approved 0.15 mg and 0.3 mg epinephrine auto-injectors. AUVI-Q is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical attention after using AUVI-Q.



An EAI with a Shorter Needle Length May Help Reduce the Risk of Certain Accidental EAI-Related Injection Injuries in Infants and Toddlers Weighing 16.5 lbs (7.5 kg) to 33 lbs (15 kg).⁹

- According to a study of 51 infants, 43 percent of children weighing 16.5 lbs (7.5 kg) to 33 lbs (15 kg) treated with a 0.15 mg EAI having a standard 12.7 mm needle length may be at risk of having the needle strike the bone.⁹
- A study suggests that for infants and toddlers weighing between 16.5 and 33 lbs (7.5-15 kg), an optimal EAI needle length of 7-8 mm is recommended.⁹

Visit www.auvi-q.com for more information.

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 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.

1. Jackson, K.D., Howie, L.D., Akinbami, L.J. (2013). Trends in allergic conditions among children: United States, 1997–2011. NCHS Data Brief, no 121. ISSN 1941–4935 2. Gupta, R.S., Springston, E.E., Warrier, M.R. et al. (2011). The prevalence, severity, and distribution of childhood food allergy in the United States. Pediatrics, 128, e9–e17. DOI: 10.1542/peds.2011-0204 3. Simons, F.E., Sampson, H.A. (2015). Anaphylaxis: Unique aspects of clinical diagnosis and management in infants (birth to age 2 years). J Allergy Clin Immunol., 135, 1125e1131. DOI: 10.1016/j.jaci.2014.09.014 4. Motosue, M.S., Bellolio, M.F., Van Houten, H.K., Shah, N.D., and Campbell, R.L. (2017). Increasing emergency department visits for anaphylaxis, 2005–2014. J Allergy Clin Immunol Pract., 5, 171–175. DOI: 10.1016/j.jaip.2016.08.013 5. Simons, F.E.R. (2007). Anaphylaxis in infants: Can recognition and management be improved? J Allergy Clin Immunol Pract 120, 537–540. DOI: 10.1016/j.jaip.2007.06.025 6. Dosanjh, A. (2013). Infant anaphylaxis: the importance of early recognition. Journal of Asthma and Allergy, 6, 103–107. DOI: 10.2147/JAA.S42694 7. Rudders, S.A., Banerji, A., Clark, S., Camargo, C.A. (2011). Age-related differences in the clinical presentation of food-induced anaphylaxis. J Pediatr., 158, 326e328. DOI: 10.1016/j.jpeds.2010.10.017 8. Dreborg, S., Wen, X., Kim, L., et al. (2016). Do epinephrine auto-injectors have an unsuitable needle length in children and adolescents at risk for anaphylaxis from food allergy? Allergy, Asthma, and Clinical Immunology. DOI: 10.1186/s13223-016-0110-8 9. Kim, H., Dinakar, C., McInnis, P. et al. (2017). Inadequacy of current pediatric epinephrine autoinjector needle length for use in infants and toddlers. Ann Allergy Asthma Immunol., 118, 719–725.e1