

**CONCERNS AND ISSUES FOR PATIENTS, PAYERS  
AND HEALTHCARE PROVIDERS**



▶ **Epinephrine Auto-Injector  
Usability**

# INDICATION AND IMPORTANT SAFETY INFORMATION



## Indication

AUVI-Q® (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise-induced anaphylaxis. AUVI-Q is intended for patients with a history of anaphylactic reactions or who are at increased risk for anaphylaxis.

## Important Safety Information

AUVI-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care. **In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care.** Each AUVI-Q contains a single dose of epinephrine for single-use injection. More than two sequential doses of epinephrine should only be administered under direct medical supervision. Since the doses of epinephrine delivered from AUVI-Q are fixed, consider using other forms of injectable epinephrine if doses lower than 0.1 mg are deemed necessary.

AUVI-Q should **ONLY** be injected into the anterolateral aspect of the thigh. Do not inject intravenously, or into buttock, digits, hands, or feet. Instruct caregivers to hold the leg of young children and infants firmly in place and limit movement prior to and during injection to minimize the risk of injection-related injury.

## INDICATION AND IMPORTANT SAFETY INFORMATION



### Important Safety Information (*continued*)

Rare cases of serious skin and soft tissue infections have been reported following epinephrine injection. Advise patients to seek medical care if they develop 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.

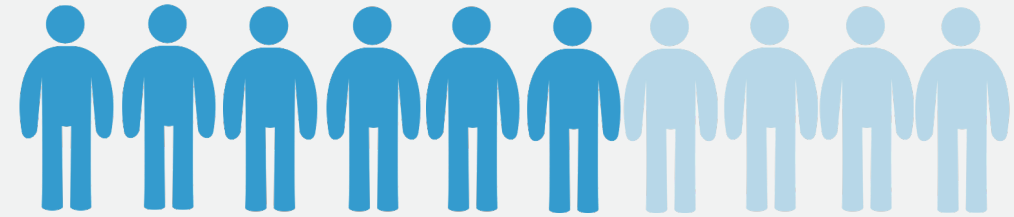
Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Common adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

Please see the full Prescribing Information for AUVI-Q<sup>®</sup> available at this presentation or at [www.auvi-q.com](http://www.auvi-q.com).

# DELAYED EPINEPHRINE TREATMENT FOR ANAPHYLAXIS *is associated with an increased risk of hospitalization, poor outcomes and even death*<sup>1-5</sup>

## REASONS WHY DELAYED USE OCCURS WITH EPINEPHRINE AUTO-INJECTORS\*:

- ▶ Approximately half of patients fail to carry their epinephrine auto-injector.<sup>6-9</sup>
- ▶ Patients and caregivers may have low confidence or fear using their epinephrine auto-injector.<sup>9-11</sup>
- ▶ A large percentage of patients use their epinephrine auto-injector incorrectly.<sup>12-15</sup>



Studies show that  
~60% of patients (≤25 years old)  
**presenting with anaphylaxis had not  
received epinephrine  
prior to arrival at the ED.**<sup>16,17</sup>

\*Data from North American studies

1. Bock SA, Muñoz-Furlong A, Sampson HA. *ds.* J Allergy Clin Immunol. 2001;107(1):191-193. 2. Fleming JT, Clark S, Camargo CA, Rudders SA. J Allergy Clin Immunol Pract. 2015;57-62. 3. Sicherer SH, Simons FER; Section on Allergy and Immunology. Pediatrics. 2017;139(3):e1-11.4. Bock SA, Muñoz-Furlong A, Sampson HA. 2001-2006. J Allergy Clin Immunol. 2007;119(4):1016-1018. 5. Yunginger JW, Sweeney KG, Sturmer WQ, et al. JAMA. 1988;260(10):1450-1452. 6. Goldberg A, et al. J Allergy Clin Immunol. 2000;106(6):1184-1189. 7. Warren CM, et al. Allergy Asthma Immunol. 2018;121(4):479-491. 8. DeMuth KA, et al. Allergy Asthma Proc. 2011;32:295-300. 9. Portnoy J, et al. J Allergy Clin Immunol Pract. 2019;7(7):2252-2261. 10. Brooks C, et al. Ann Allergy Asthma Immunol. 2017;119(5):467-468/ 11. Chad L, Ben-Shoshan M, Asai Y, et al. Allergy. 2013;68(12):1605-1609. 12. Bonds RS, et al. Ann Allergy Asthma Immunol. 2015;114(1):74-76.e2. 13. Sicherer SH, et al. Pediatrics. 2000;105(2):359-363. 14. Camargo CA Jr, Guana A, Wang S, et al. J Allergy Clin Immunol Pract. 2013;1(3):266-272.e1-3. 15. Kessler C, Edwards E, Dissinger E, Sye S, Visich T, Grant E. Ann Allergy Asthma Immunol. 2019;123(3):256-262.c 16. Robininson M, et al. Ann Allergy Asthma Immunol. 2017;119(2):164-16. 17. Trainor JL, Pittsenbarger ZE, Joshi D, Adler MD, Smith B, Gupta RS. [published online ahead of print, 2020 Jun 15]. Pediatr Emerg Care. 2020;10.1097/PEC.0000000000002146. doi:10.1097/PEC.0000000000002146

## USABILITY STUDY: *AUVI-Q vs EpiPen®*

- ▶ The study highlights the importance of device design on successful epinephrine administration.

As this was a simulated use study, participants may not have experienced the same level of stress that they might experience during anaphylaxis. Clinical significance is not known. This study was conducted by kaleo, Inc.

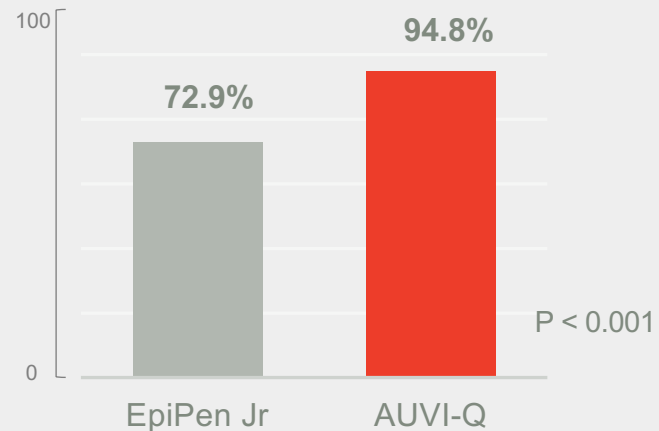
### STUDY DESIGN:

- ▶ In a human factors usability study, untrained adults aged 18-65 years (N = 96) used 0.15 mg AUVI-Q and EpiPen Jr® trainers to simulate epinephrine administration to a child-sized manikin.
- ▶ The participants had no experience with nor training to use an injection device. Individuals with any potential experience administering an epinephrine auto-injector with any knowledge of injection devices were excluded from the study.
- ▶ Only written instructions on the device label and/or device voice instructions were available to participants.
- ▶ After completing a simulation with one device (chosen randomly), participants were presented the same allergic emergency-use scenario with the other EAI.

# USABILITY STUDY: AUVI-Q vs EpiPen®

## RESULTS:

▶ **Significantly more** untrained adults completed key injection tasks with AUVI-Q.



Key injection tasks were defined as the minimum tasks required for a patient to receive an epinephrine dose.

**No accidental injections** would have occurred with AUVI-Q.

SIMULATED-FINGER OR HAND-INJECTION ERRORS

**14.6 %**  
EpiPen Jr

VS

**0%**  
AUVI-Q

14.6% of the *untrained adults would have accidentally injected epinephrine into their finger or hand using EpiPen Jr.*

*No accidental injection errors would have occurred with AUVI-Q based on this use scenario.*

## PREFERENCE DATA *for AUVI-Q*

- ▶ A study to determine whether adults, caregivers, and children prefer using the AUVI-Q device compared to EpiPen<sup>®</sup>.

### STUDY DESIGN:

- ▶ A study of 693 people aged 11 to 65 years was conducted to determine whether adults (N=241) caregivers (N=228), and children (N=224) with and without EAI experience prefer using the AUVI-Q device compared to the EpiPen<sup>®</sup> (epinephrine injection, USP).
- ▶ Participants completed simulated-use tests of AUVI-Q and EpiPen<sup>®</sup>. The two devices were presented randomly to the participant in 2 brown paper bags to avoid bias, and devices were tested individually.
- ▶ Participants were not given any information on how to use the EAI beyond the instructions that come with the device.

Study funded by Sanofi

Camargo CA Jr, Guana A, Wang S, et al. Auvi-Q versus EpiPen: preferences of adults, caregivers, and children. J Allergy Clin Immunol Pract. 2013;1(3):266-272.e1-3.

 **Auvi-Q**<sup>®</sup>  
epinephrine injection, USP

CM-US-AQ-2185

# PREFERENCE DATA *for AUVI-Q*

## RESULTS:

On completion of testing both devices individually, participants were presented with both devices simultaneously and asked to complete a survey to indicate their preference between AUVI-Q and EpiPen or to indicate no preference.

- ▶ AUVI-Q was significantly ( $P < 0.001$ ) preferred over EpiPen® in all primary and secondary end points.

