In Brief: Auvi-Q Epinephrine Auto-Injector for Infants and Toddlers

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IN BRIEF

Auvi-Q Epinephrine Auto-Injector for Infants and Toddlers

The FDA has approved a lower-dose epinephrine auto-injector (Auvi-Q 0.1 mg – Kaléo) for emergency treatment of anaphylaxis in children weighing 7.5-15 kg (16.5-33 lbs). It is the first epinephrine auto-injector to be approved for use in infants and toddlers weighing less than 15 kg. Previously, Auvi-Q and other epinephrine auto-injectors were only available in 0.15- and 0.3-mg strengths for patients weighing 15-30 kg or ≥30 kg, respectively.1

Table 1. Epinephrine Auto-Injectors

<table>
<thead>
<tr>
<th>Epinephrine Injection, USP</th>
<th>Formulations</th>
<th>Cost</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>generic (Mylan)3</td>
<td>0.15 mg/0.3 mL, 0.3 mg/0.3 mL</td>
<td>$300.00&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>EpiPen Jr (Mylan)</td>
<td>0.15 mg/0.3 mL, 0.3 mg/0.3 mL</td>
<td>608.60&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>EpiPen</td>
<td>0.3 mg/0.3 mL</td>
<td>608.60&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>generic (Impax)&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0.15 mg/0.15 mL, 0.3 mg/0.3 mL</td>
<td>395.20&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Auvi-Q (Kaléo)&lt;sup&gt;8&lt;/sup&gt;</td>
<td>0.1 mg/0.1 mL, 0.15 mg/0.15 mL, 0.3 mg/0.3 mL</td>
<td>4900.00&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Symjepi (Adamis)&lt;sup&gt;10&lt;/sup&gt;</td>
<td>0.3 mg/0.3 mL</td>
<td>N.A.</td>
<td></td>
</tr>
</tbody>
</table>

N.A. = cost not available at time of publication
1. The dose of epinephrine is 0.1 mg for patients who weigh 7.5-15 kg, 0.15 mg for those who weigh 15-30 kg, and 0.3 mg for those who weigh ≥30 kg.
2. Approximate WAC for one package containing two auto-injectors. WAC = wholesaler acquisition cost or manufacturer’s published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. May 6, 2018. Reprinted with permission by First Databank, Inc. All rights reserved. ©2018. www.fdbhealth.com/policies/drug-pricing-policy.
3. Interchangeable with EpiPen and EpiPen Jr.
4. The manufacturer provides free epinephrine auto-injectors to eligible uninsured or underinsured patients who are from families earning up to 400% of the federal poverty level (https://aspe.hhs.gov/poverty-guidelines).
5. All strengths cost the same.
6. Authorized generic of Adrenaclick, which has been discontinued. Similar to EpiPen and EpiPen Jr in size and functionality, but not considered interchangeable due to differences in device design and instructions for use.
7. Both strengths are available at discounted prices at some pharmacies (at CVS pharmacies, the cash price is $110.00 for a package containing two auto-injectors).
8. Auvi-Q is not interchangeable with other currently available epinephrine auto-injectors.
9. According to the manufacturer, the out-of-pocket cost is $0 for all commercially insured patients, whether or not their insurer covers the $4900 for the device. The cash price for patients without government or commercial insurance is $360 for those with a household income ≤$100,000/year and $0 for those with a household income >$100,000/year.
10. Approved by the FDA, but not yet marketed as of May 2018.

The recommended dose of epinephrine for intramuscular (IM) or subcutaneous (SC) administration is 0.01 mg/kg. None of the previously available epinephrine auto-injectors provided a weight-appropriate dose for infants, so many physicians prescribed a 0.15-mg auto-injector off-label for this age group.2

The Auvi-Q device is about the length and width of a credit card and as thick as a cell phone. It has an automatic needle retraction system and a red safety guard at the needle-end of the device. Removal of the outer case initiates visual signals and an audio recording that provides step-by-step instructions and a 2-second countdown during the injection process.

Auvi-Q should be injected IM into the anterolateral aspect of the thigh (through clothing, if necessary). After treatment with epinephrine, the patient should be taken to the nearest emergency department; anaphylaxis symptoms recur in up to 15% of patients hours after resolution of the initial symptoms.3

The needle length in the new 0.1-mg auto-injector is shorter than in other epinephrine auto-injectors. Use of a shorter needle decreases the risk of striking bone when administering a dose to a small child, but may result in SC rather than IM injection.4,5 Higher levels of epinephrine are obtained with IM injection than with SC injection.6

Auvi-Q 0.1 mg is supplied in a carton containing two single-use auto-injectors and a training device without a needle. The outer case protects the epinephrine solution from light; exposure to excessive heat or cold should be avoided. The shelf-life of the epinephrine in the auto-injector is 18 months. All three strengths of Auvi-Q are priced the same.
