EpiPen Auto-injector Shortage
2019 Update

Pfizer Canada is reporting possible future shortage of Epipen 0.3 mg auto-injectors; while a shortage is not inevitable, supply is unstable and Pfizer is taking steps to mitigate. Pfizer reports Epipen Jr is unaffected.

There is only one Canadian supplier of epinephrine auto-injectors:

<table>
<thead>
<tr>
<th>DIN</th>
<th>Manufacturer</th>
<th>Product</th>
<th>Strength</th>
<th>Stock at McKesson - 24 Jul 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>00509558</td>
<td>Mylan Specialty LP</td>
<td>EpiPen</td>
<td>0.3 mg/0.3 ml</td>
<td>√ - may become depleted</td>
</tr>
<tr>
<td>00578657</td>
<td>Mylan Specialty LP</td>
<td>EpiPen Jr</td>
<td>0.15 mg/0.3 ml</td>
<td>√</td>
</tr>
</tbody>
</table>

Based on an interim order allowing importation of epinephrine products, another auto-injector product is available on the Canadian market:

<table>
<thead>
<tr>
<th>DIN</th>
<th>Manufacturer</th>
<th>Product</th>
<th>Strength</th>
<th>Stock at McKesson- 24 Jul 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>02480379</td>
<td>MSD/Kaleo</td>
<td>Auvi-Q</td>
<td>0.3 mg/0.3 ml</td>
<td>√</td>
</tr>
<tr>
<td>02480360</td>
<td>MSD/Kaleo</td>
<td>Auvi-Q</td>
<td>0.15 mg/0.15 ml</td>
<td>√</td>
</tr>
</tbody>
</table>

Suppliers of epinephrine 1 mg/ml ampoules:

<table>
<thead>
<tr>
<th>DIN</th>
<th>Manufacturer</th>
<th>Product</th>
<th>Stock at McKesson- 24 Jul 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>02435810</td>
<td>Teligent OU</td>
<td>Epinephrine Injection</td>
<td>10x1 ml amps</td>
</tr>
<tr>
<td>00155357</td>
<td>ERFA Canada</td>
<td>Adrenalin</td>
<td>Only available in 30 ml vials; no stock of 10x1 ml amps</td>
</tr>
<tr>
<td>00721891</td>
<td>Pfizer Canada</td>
<td>Epinephrine Injection</td>
<td>10x1 ml amps</td>
</tr>
</tbody>
</table>

Management of shortage

Auto-injectors:
- Switch to Auvi-Q. Health Canada expects the existing EpiPen and Auvi-Q inventories to be sufficient to meet Canadian demands.
- Should both EpiPen and Auvi-Q 0.3 mg auto-injectors become unavailable:
  - EpiPen Jr. and Auvi-Q 0.15 mg are currently available and not expected to be affected. Adults and older children can use two 0.15 mg auto-injectors. (Disadvantages: two injections, doubling of the cost.)
  - Advise patients to use the product they currently have on hand even if it is expiring. EpiPens expire on the last day of the month indicated on the product packaging. Health Canada advises anyone having a reaction to USE THEIR EXPIRED PRODUCT and immediately call 911.
There are some stability data of EpiPen devices: two studies indicate most (97.2%) devices retained at least 90% of labeled concentrations for up to 24 months past the labeled expiry date.\(^4,5\) Another study does not provide detailed results but the range of retained concentrations was 51-102% with the most outdated product (51 months past expiry date) retaining the lowest concentration.\(^6\)

**Manual injections:**

*In 2018, SCPP temporarily amended the scheduling of epinephrine ampoules from Schedule I to Schedule II. As this amendment was not extended, epinephrine ampoules are Schedule I.*

**In-pharmacy preparation of anaphylactic kit**\(^7\)

*Anaphylactic kit with epinephrine ampoules*

- Patients /caregivers will fill syringes with epinephrine from ampoules in the kit immediately prior to injection if / when needed.
- 2 – 1 cc syringes and 2 needles. (Note, filter needles are not necessary when patients or caregivers will be drawing up medication from ampoules for injection in an emergency situation.)
  - Needle gauge and length:
    - Infants < 18 months, 25 – 27 G, 5/8 – 1¼ inch
    - Children > 18 months up to 18 years, 23 – 25 G, 5/8 to 1¼ inch
    - Adult 23 – 25 G, 1 to 1¼ inch
- 2 extra needles
- 2 ampoules of epinephrine 1:1,000
- Alcohol swabs, cotton balls, gauze pads
- Small sharps container (Optional)
- Case to hold syringes (e.g., pencil case, eyeglass case)
- Provide directions on filling syringes, where and how to administer injection, safe disposal of ampoules, needles, syringes, etc.\(^8\) (Appendix 1)

*Note: Earlier versions of this document provided information about prefilling syringes. At this time, and due to potential safety concerns, SCPP does not recommend the compounding of a substitute product by pharmacies in Saskatchewan.*

**Instructional videos:**

- Directions for patients on filling syringes and injecting epinephrine Note: in emergency situations, such as anaphylaxis, the IM injection can be administered through clothing.\(^9\)

---

Prepared by K. Jensen MSc, BSP; reviewed by C. Bell BSP
medSask | 25 Jan 2018
Updated 24 Jul 2019
Appendix 1
Patient directions for preparing and administering an epinephrine injection
https://www.youtube.com/watch?v=mD9biX1pn3M&feature=youtu.be

1. Open the epinephrine ampoule:
   - Tap the top of the ampoule and swirl to ensure all the medication is at the bottom of the ampoule.
   - Use two alcohol swabs (or two small gauze squares) to open the ampoule. Hold the “head” (top) of the ampoule with one swab and the “body” (bottom portion) with the other and pushing away from your body, firmly snap the top off the ampoule. Discard the top and set the ampoule carefully on a level surface.

2. Draw epinephrine into syringe:
   - Remove the shield from the needle.
   - Pick up the ampoule, tilt it down and insert the needle tip into opening. Pull on the syringe plunger and draw up slightly more than 0.3 ml of epinephrine into the syringe and remove the needle from the ampoule.
   - Point the needle to the sky or ceiling, gently tap on the syringe a few times, then push the plunger up to the 0.3 ml mark to remove air and excess epinephrine. It is not necessary to remove all the air because the injection is going into a muscle.

3. Give the injection:
   - Push the needle firmly into the outer side of the upper thigh at a 90 degree angle. The injection can be given through clothing if necessary. Push the plunger in all the way. Hold the syringe in place for 3 seconds, then remove from thigh.

4. If no improvement or symptoms get worse, another injection can be given 5 to 15 minutes after the first injection.

5. Carefully dispose of the ampoule glass, syringe and needles, ideally in a sharps container.

References:

© medSask 2019