EpiPen® (Epinephrine), EpiPen Jr and Authorized Brand Alternatives - Safety Alert

Effective Date: March 24, 2020

On March 24, 2020, the FDA announced that administration of Pfizer and Mylan’s EpiPen (Epinephrine) and EpiPen Jr auto-injectors, and their authorized brand alternative versions may be delayed or prevented during an emergency due to:

- Device failure from spontaneous activation caused by using a sideways force to remove the blue safety release
- Device failure from inadvertent or spontaneous activation due to a raised blue safety release
- Difficulty removing the device from the carrier tube
- User errors

Refer to the reference for additional details around the identified administration issues.

Since EpiPen is administered for severe and potentially life-threatening allergic reactions, anything that prevents or delays the administration of the intended dose of epinephrine could result in a high risk to the patient, including the risk of death.

It is vital for lifesaving products to work as designed in an emergency situation and patients and caregivers should inspect their epinephrine auto-injector prior to needing it to ensure the blue safety release is not raised and that the device can be easily removed from the carrier tube.

**Pharmacists should inspect the products before dispensing them to patients to ensure quick access to the auto-injector and should not dispense any product which does not easily slide out of its carrier tube or has a raised blue safety release.**

As stated on the product label, consumers should always seek emergency medical help right away after using their epinephrine auto-injector.

Patients should contact Mylan Customer Relations at 1-800-796-9526 (8 AM – 5 PM EST, Monday through Friday) if they find an issue with their epinephrine auto-injector and to obtain a replacement at no additional cost.

### EpiPen and EpiPen Jr Products

<table>
<thead>
<tr>
<th>Product Description</th>
<th>NDCs</th>
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<tbody>
<tr>
<td>EpiPen 0.3 mg auto-injector</td>
<td>49502-500-02 (authorized brand alternative NDC: 49502-102-02)</td>
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<tr>
<td>EpiPen Jr 0.15 mg auto-injector</td>
<td>49502-501-02 (authorized brand alternative NDC: 49502-101-02)</td>
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**References:**