Central California Alliance for Health

Provider News

April 12, 2017

# EpiPen and EpiPen Jr. Recall

Mylan has voluntarily recalled 13 lots of EpiPen and EpiPen Jr. (epinephrine injection), 0.3 mg and 0.15 mg strengths. The recall is being conducted due to the potential that devices may contain a defective part that may result in the device being difficult to activate in an emergency (failure to activate or increased force needed to activate) and could have significant health consequences for a patient experiencing anaphylaxis.

Mylan and the United States Food and Drug Administration (FDA) announced the following:

- This recall is being conducted as a result of the receipt of two previously disclosed reports outside of the U.S. of failure to activate the device due to a potential defect in a supplier component.
- **Please note that not all members using these medications will be affected, since this drug recall pertains to only 13 lots of Epipen and Epipen Jr.** Patients will need to check the lot number listed on the package to clarify if their injector is affected by this recall.

| Product/Dosage | NDC # (Carton) | NDC # ( Device) | Lot # | Expiration Date |
|---|---|---|---|---|
| EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg | 49502-501-02 | 49502-501-01 | 5GN767 | April 2017 |
| EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg | 49502-501-02 | 49502-501-01 | 5GN773 | April 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 5GM631 | April 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 5GM640 | May 2017 |
| EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg | 49502-501-02 | 49502-501-01 | 6GN215 | September 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM082 | September 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM072 | September 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM081 | September 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM088 | October 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM199 | October 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM091 | October 2017 |
| EpiPen 2-Pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM198 | October 2017 |
| EpiPen 2-pak® Auto-Injectors, 0.3 mg | 49502-500-02 | 49502-500-01 | 6GM087 | October 2017 |

Health care professionals and patients are encouraged to report adverse events related to the use of Epipen or Epipen Jr. to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call (800) 332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to (800) FDA-0178.

For additional assistance, please contact Mylan Customer Relations at (800) 796-9526 or customer.service@mylan.com. Mylan has agreed to replace recalled devices at no cost to the patient. Additional information is available at https://www.fda.gov/Safety/Recalls/ucm550173.htm. The Alliance Pharmacy department appreciates your efforts to provide high quality care to Alliance members.