



Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2017-04

APRIL 4, 2017

**ITEM:
SPECIFIC
INCIDENT(S):**

EpiPen and and EpiPen Jr Auto-Injector: Recall - Failure to Activate Device

**GENERAL
INFORMATION:**

- Mylan Pharmaceuticals Inc. announced a voluntary recall of specific lots of EpiPen (epinephrine injection, USP) and EpiPen Jr (epinephrine injection, USP) Auto-Injectors due to the potential of a defective part in the devices that may result in failure to activate.
- EpiPen and EpiPen Jr (epinephrine injection) Auto-Injector products are used for emergency treatment of severe allergic reactions, including anaphylaxis.
- The recall impacts the 0.3 mg and 0.15 mg strengths of EpiPen Auto-Injector.
- While the number of reported failures is small (2 reports outside of the U.S.), there is potential for life-threatening risk if a severe allergic reaction or anaphylaxis goes untreated because of difficulty of activating the device (failure to activate or increased force needed to activate) in an emergency.
- Affected lots include:

PRODUCT/DOSAGE	NDC NUMBER	LOT NUMBER	EXPIRATION DATE
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM087	October 2017

- The recalled product was manufactured by Meridian Medical Technologies and distributed by Mylan Specialty between December 2015 and July 2016.
- None of the recalled lots include the authorized generic for EpiPen Auto-Injector, which is also manufactured by Meridian Medical Technologies.
- This recall is an extension of the product sequestration actions in **Product Recall Office Log # 11809** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of EpiPen

(epinephrine injection, USP) and EpiPen Jr (epinephrine injection, USP) Auto-Injectors by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, Allergy and Immunology specialists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 04/18/2017):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
 - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at: <https://vawww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - It is important that patients continue to carry their current EpiPen Auto-Injector until they receive a replacement device.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
 - Communicate to PBM/VAMedSAFE that all patient notification actions

have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: FDA

REFERENCE(S): FDA Safety Alert. EpiPen and and EpiPen Jr Auto-Injector: Recall - Failure to Activate Device.
Available at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm550165.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
(Accessed 03/31/2017).

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.

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