

EpiPen Auto-Injector Safety Alert

Date of Notice: 03/24/2020

Brief Description of Safety Alert

On March 24, 2020, the FDA issued an alert to patients, caregivers and health care professionals that EpiPen 0.3mg and EpiPen Jr 0.15mg auto-injectors, and the authorized generic versions, may potentially have delayed injection or be prevented from properly injecting due to:

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

A very limited number of EpiPen devices may have a blue safety release that is slightly raised. If the blue safety release is raised, the device may activate prematurely, which could potentially delay or prevent emergency treatment when needed.

Additionally, in some cases EpiPen devices may not slide out of their carrier tube easily, or potentially at all, due to a slight deformation on the rim of the carrier tube. The carrier tube is the immediate package in which the auto-injector is contained. In some cases, the patient or caregiver may not be able to quickly remove the auto-injector from the carrier tube.

Examples of specific user errors that can delay or prevent the administration of the intended dose of epinephrine include:

- The device will not activate if the blue safety release is in place
- Ensure the needle end (orange end of the device) is in contact with the outer thigh (upper leg) prior to and during activation. The EpiPen device should be administered by swinging and pushing firmly against the outer thigh until it “clicks.” This signals that injection has started.
- Ensure the device is held in place for a minimum of three seconds following activation.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
EpiPen 0.3mg auto-injector	All NDCs	All lots	All dates
EpiPen Jr 0.15mg auto-injector	All NDCs	All lots	All dates
epinephrine 0.3mg auto-injector	All NDCs	All lots	All dates
epinephrine Jr 0.15mg auto-injector	All NDCs	All lots	All dates

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

Prescriber Information

It is important for health care providers, patients, and caregivers to periodically review the EpiPen user instructions and practice using the EpiPen trainer to ensure proper understanding and utilization of the EpiPen auto-injector.

FDA is aware of adverse event reports associated with EpiPen products. FDA asks health care professionals and consumers to report any adverse reactions or quality problems to the FDA's MedWatch program:

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 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 1-800-FDA-0178

Member Information

Patients should contact Mylan Customer Relations at 800-796-9526 if they find an issue with their auto-injector and to obtain a replacement at no additional cost.

RxAdvance Response

RxAdvance encourages members to periodically review their EpiPen to ensure its quality. Please contact your prescriber or pharmacist if you have questions regarding the use of your EpiPen.

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