AAP News™

FDA: Inspect epinephrine auto-injectors to head off problems

March 25, 2020

Trisha Korioth, Staff Writer

Article type: News

Topics: Allergy/Immunology, Patient Education/Patient Safety/Public Education

---

The Food and Drug Administration (FDA) is warning that EpiPen 0.3 mg, EpiPen Jr. 0.15 mg and the authorized generic versions of the epinephrine products may have delayed injection or be prevented from proper injection.

The FDA urges people to inspect their epinephrine auto-injectors before a life-threatening emergency to make sure the blue safety release is not raised and that they can remove the device easily from the carrier tube.

Pfizer and Mylan issued a letter to health care providers on March 23 involving the brand and generic versions.

The devices can fail due to:

- spontaneous activation when sideways force is used to remove the blue safety release,
- inadvertent or spontaneous activation due to a raised blue safety release, or
- difficulty removing the device from the tube because of a slight deformation on the rim of the carrier tube.

The safety communication also offers reminders about user errors that prevent the device from operating properly.

- Do not try to activate the device with the blue safety release in place.
- Make sure the needle end of the device is in contact with the outer thigh before and during activation.
- Make sure the device is held in place for a minimum of three seconds following activation.

EpiPen's National Drug Code (NDC) is 49502-500-02, and the authorized generic NDC is 49502-102-02. The NDC for EpiPen Jr. 0.15 mg is 49502-501-02, and the NDC for its authorized generic is 49502-101-02.

Patients who find an issue with their device should contact Mylan at 800-796-9526 for a free replacement. Report any adverse reactions or quality problems to the FDA's MedWatch program at www.fda.gov/medwatch/report.htm. Read the safety communication at https://bit.ly/2UzRsSS.