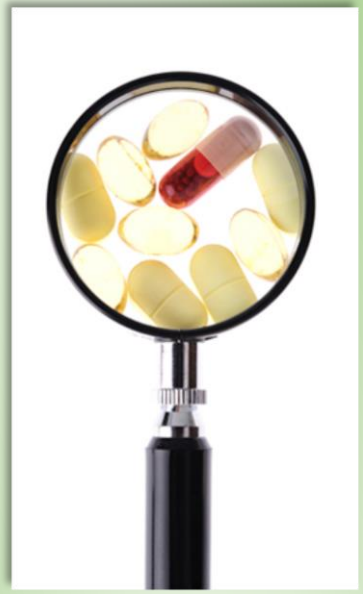
March 25, 2020 COM-2020-020

DRUG SAFETY NOTIFICATION



DATE: 3/24/2020

DRUG NAME: EpiPen 0.3mg and EpiPen Jr 0.15mg auto-injectors, and the authorized generic

DRUG INDICATION: Anaphylaxis, Hypotension - Septic shock, Intermittent Asthma, Temporary relief of mild symptoms

SAFETY TOPIC: Errors related to device malfunctions and user administration

Dear provider of pharmaceutical services,

At PharmPix we are compromised to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on March 24, 2020, the U.S. Food and Drug Administration (FDA) published a safety communication for EpiPen 0.3mg and EpiPen Jr 0.15mg auto-injectors, and the authorized generic versions, indicating that they may potentially have delayed injection or be prevented from properly injecting due to device failure from inadvertent or spontaneous activation, difficulty removing the device from the carrier tube, and/or user errors.

RECOMMENDATION FOR PHARMACISTS:

- Periodically review the EpiPen user instructions and practice using the EpiPen trainer to ensure proper understanding and utilization of the EpiPen.
- Inspect the products before dispensing them to patients to ensure quick access to the auto-injector. Do not dispense if the device does not easily slide out of its carrier tube or has a raised blue safety release.

Remember that any adverse events or side effects related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm

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- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

Additional information can be found at the FDA's Drug Safety and Availability portal (https://www.fda.gov/drugs/drug-safety-and-availability).

Best regards,

PharmPix Clinical Department

Reference:

- Center for Drug Evaluation and Research. (2020, March 24). FDA alerts patients and health care professionals of EpiPen. Retrieved March 25, 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device?utm_campaign=FDA MedWatch - EpiPen Auto-injector by Pfizer and Authorized Generic Versions&utm_medium=email&utm_source=Eloqua

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