**June 4, 2020** **COM-2020-042**

# DRUG SAFETY NOTIFICATION

**DATE: June 1, 2020**

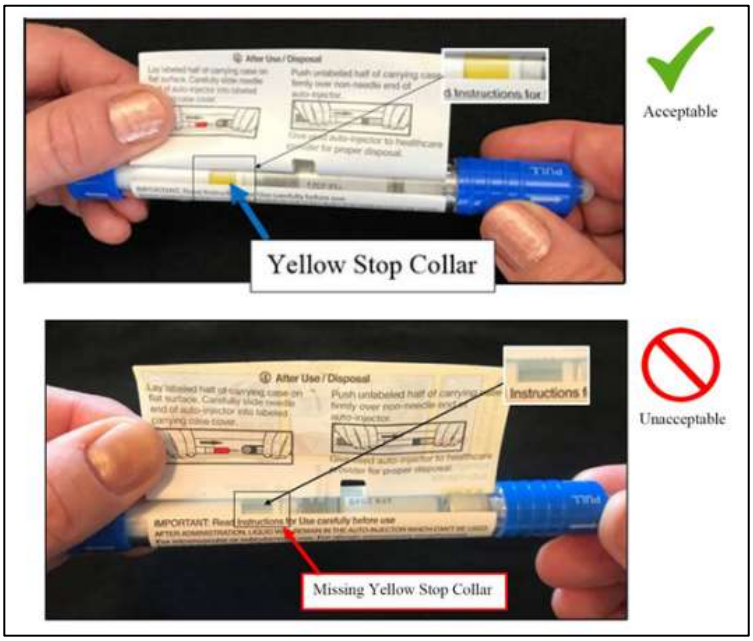
**DRUG NAME: Epinephrine auto-injector 0.3 mg**

**DRUG INDICATION: Emergency treatment of allergic reactions (Type I) including anaphylaxis**

**SAFETY TOPIC: FDA alerts about device malfunction**

**Dear provider of pharmaceutical services,**

PharmPix is committed to the health and wellness of our members. 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 June 1, 2020 the US Food and Drug Administration (FDA) published a safety communication for Epinephrine Auto-Injector Devices produced by Amneal Pharmaceuticals and Impax Laboratories, due to possible malfunctions. The FDA is alerting healthcare professionals, patients, and caregivers to immediately inspect certain lots of Amneal and Impax epinephrine auto-injector 0.3 mg to ensure the yellow "stop collar" in the device is present.




(Image obtained from: https://www.fda.gov/safety/medical-product-safety-information/epinephrine-auto-injector-devices-amneal-and-impax-cder-alert-fda-alerts-patients-and-health-care)



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If the auto-injector is missing the yellow "stop collar" component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient.

Recommendations for healthcare professionals:

- If you have received Amneal or Impax's epinephrine auto-injector after December 20, 2018, you should immediately visually inspect the auto-injector to confirm the presence of the yellow "stop collar" by:
    - Removing the auto-injector from the carrying case.
    - Placing the auto-injector on a flat surface.
    - Locating the edge of the label that states, "Peel here for further instructions." Lift the label edge until you see the clear part of the auto-injector.
    - Looking for the yellow "stop collar" inside the clear part of the auto-injector. If the yellow "stop collar" is not visible inside the clear part of the auto-injector, gently rotate the blue sheath remover, without pulling or removing the blue sheath remover, to observe if the yellow "stop collar" comes into view inside the clear part of the auto-injector.
    - If yellow "stop collar" is present, then the product is safe to use, and no further action is necessary. Re-wrap the label to its original position and place the auto-injector into the carrying case.
- Read FDA's letter to healthcare professionals for full details, including affected lots, step by step visual inspections instructions, and additional actions to take.
- Pharmacists should inspect the products before dispensing them to patients.
- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
    - Complete and submit the MedWatch Online Voluntary Reporting Form online.
    - Download FDA Form 3500 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.





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Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program and FDA's Drug Safety and Availability portal.

Best regards,

PharmPix Clinical Department

Reference(s):


- Epinephrine Auto-Injector Devices by Amneal and Impax: CDER Alert. U.S. Food and Drug Administration. (2020). Retrieved 4 June 2020, from https://www.fda.gov/safety/medical-product-safety-information/epinephrine-auto-injector-devices-amneal-and-impax-cder-alert-fda-alerts-patients-and-health-care.
- FDA Alerts of Amneal & Impax Epinephrine device issue. U.S. Food and Drug Administration. (2020). Retrieved 4 June 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-amneal-and-impax-laboratories-epinephrine-auto.




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