

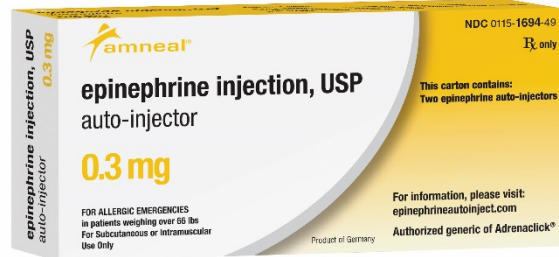
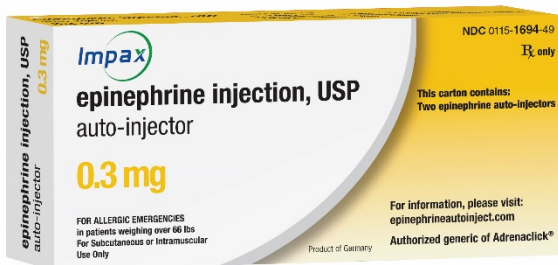


June 1, 2020

**IMPORTANT SAFETY INFORMATION**  
**Impax Laboratories, LLC**  
**Epinephrine Injection, USP Auto-Injector 0.3 mg**

**PRODUCT SAFETY ADVISORY**

Epinephrine Injection, USP Auto-Injector 0.3 mg may be missing its yellow “stop collar,” potentially causing medication overdose.



Dear Healthcare Provider:

Impax Laboratories, LLC, a wholly owned subsidiary of Amneal Pharmaceuticals LLC, is providing important safety information concerning its Epinephrine Injection, USP Auto-Injector 0.3 mg. The affected NDC numbers are 0115-1694-30 (case) and 0115-1694-49 (carton). Impax is writing to inform you that some Epinephrine Injection, USP Auto-Injector 0.3 mg devices may not contain the yellow “stop collar” component. The yellow “stop collar” is one of several components that work together to assure proper dosing of the auto-injector. If the auto-injector is missing a yellow “stop collar” component, the auto-injector has the potential safety risk of delivering an overdose (0.6 mg instead of the intended 0.3 mg) of the product to a consumer. An overdose of epinephrine has the potential to cause severe patient harm or death.

A list of the affected lots is included below.

If you are a pharmacist and have dispensed Impax's Epinephrine Injection, USP Auto-Injector 0.3 mg since December 20, 2018, Impax is requesting that you *contact all consumers who received the product* and provide them with the attached "Dear Consumer Letter" which includes visual inspection instructions.

If you are a pharmacist or a healthcare provider and currently have inventory from the affected lots (listed at the end of this letter) of Impax's Epinephrine Injection, USP Auto-Injector 0.3 mg, please perform a visual inspection (Steps 1-5) as described below to confirm the presence of the yellow "stop collar".

- If the visual inspection indicates the presence of the yellow "stop collar," then no action is required.
- If the yellow "stop collar" is missing, then please contact Amneal Pharmaceuticals Drug Safety Department, using the contact information below, to make arrangements for the return of the auto-injector and a replacement at no additional cost:

**AMNEAL PHARMACEUTICALS DRUG SAFETY DEPARTMENT**

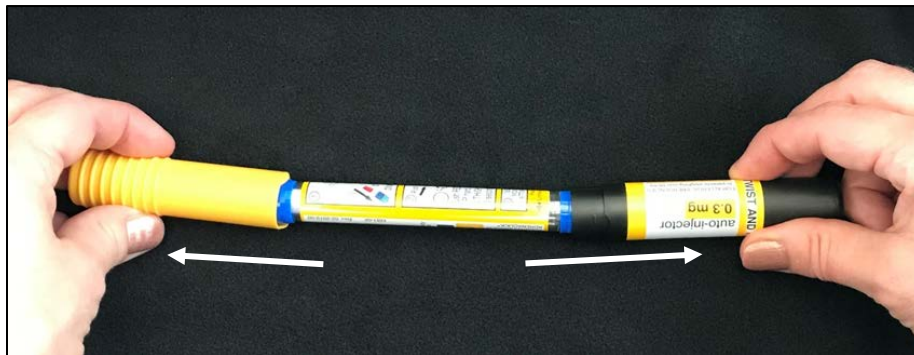
Phone: 1 (877) 835-5472

Email: [Drugsafety@amneal.com](mailto:Drugsafety@amneal.com)

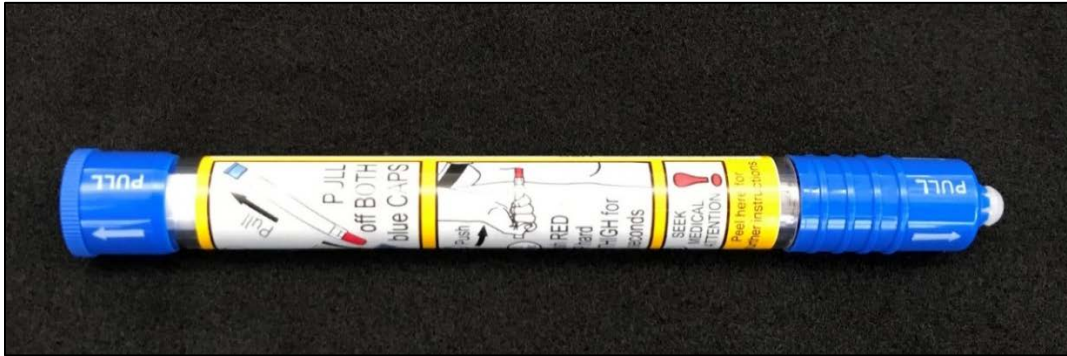
Mail: Amneal Pharmaceuticals, 50 Horseblock Road, Brookhaven, New York 11719

## VISUAL INSPECTION INSTRUCTIONS TO CONFIRM PRESENCE OF YELLOW “STOP COLLAR”

**Step 1:** Remove the auto-injector from the carrying case.



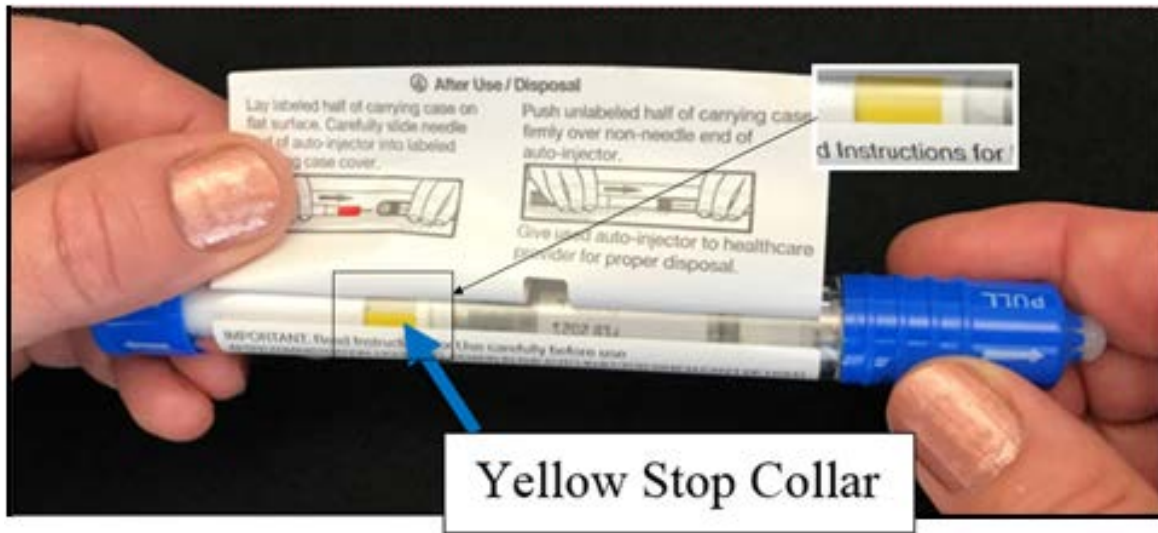
**Step 2:** Place the auto-injector on a flat surface as shown below.



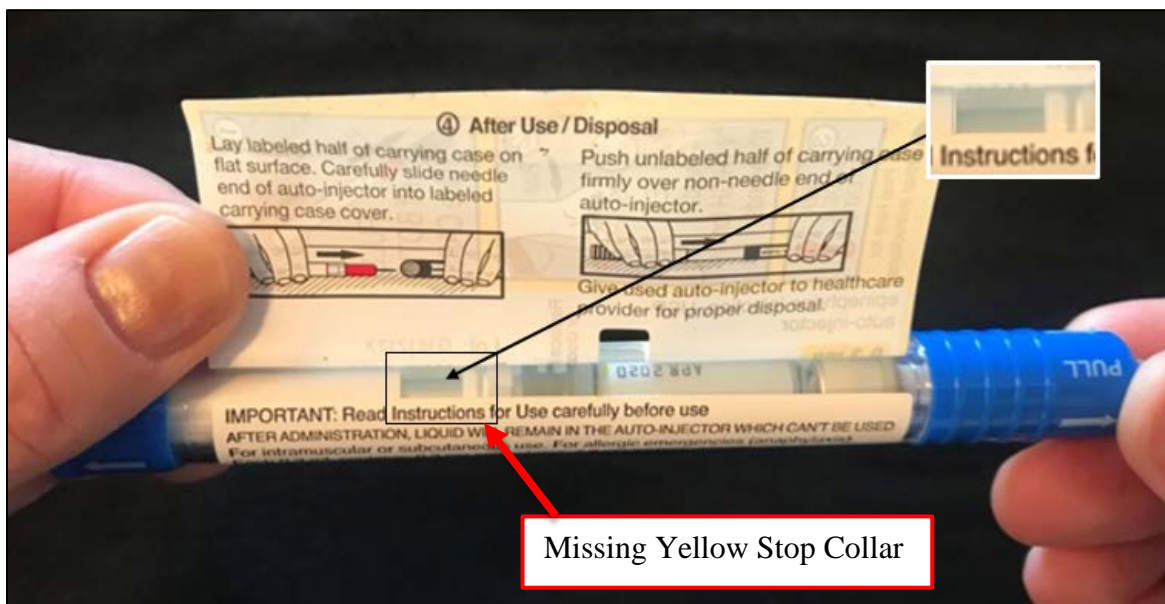
**Step 3:** Locate the edge of the label that states “Peel here for further instructions”. Lift the label edge until you see the clear part of the auto-injector.



**Step 4:** Look for the YELLOW “stop collar”. See arrow below.

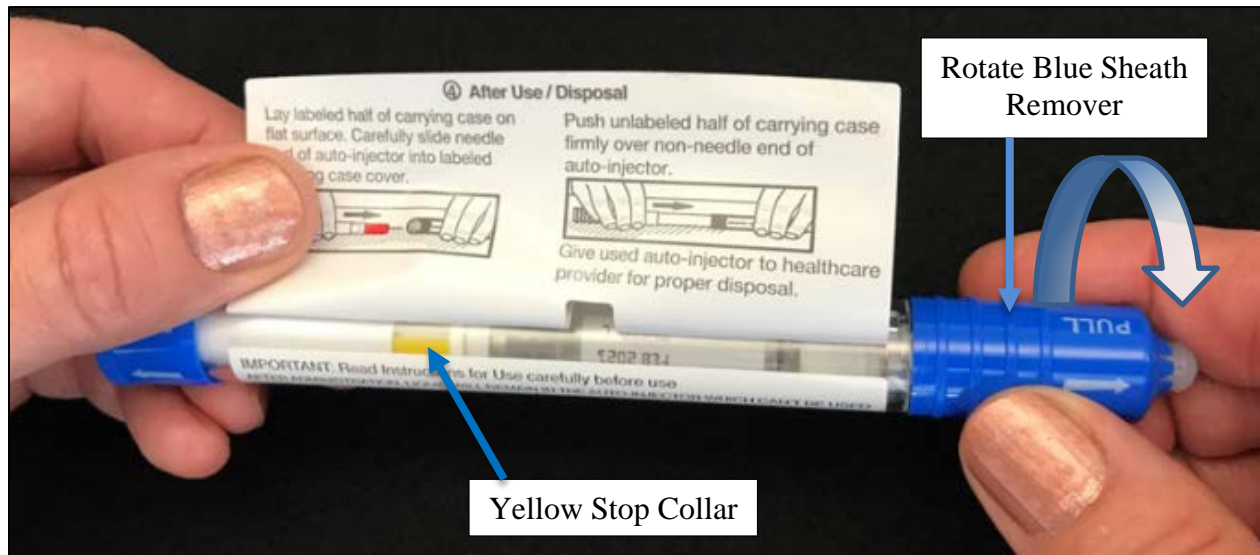


✓  
Acceptable



⊘  
Unacceptable

**PLEASE NOTE:** If the yellow “stop collar” is missing, hold the unit (as shown below) and gently rotate the blue sheath remover and observe until the yellow “stop collar” comes into view. **DO NOT PULL OR REMOVE THE BLUE SHEATH REMOVER.**



**IMPORTANT:**

- **If yellow “stop collar” is present**, retain product in inventory for future dispensing. No further action is necessary.
- **If yellow “stop collar” is missing**, contact Amneal Pharmaceuticals Drug Safety Department. **DO NOT DISPENSE THE AUTO-INJECTOR.**

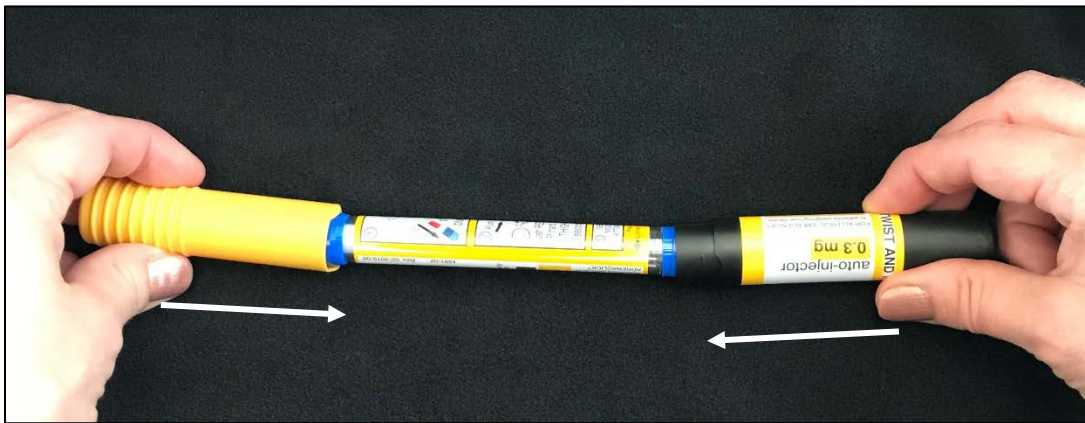
**AMNEAL PHARMACEUTICALS DRUG SAFETY DEPARTMENT**

Phone: 1(877) 835-5472

Email: [Drugsafety@amneal.com](mailto:Drugsafety@amneal.com)

Mail: Amneal Pharmaceuticals, 50 Horseblock Road, Brookhaven, New York 11719

**Step 5:** Re-wrap the label to its original position and place the auto-injector into the carrying case.



To report adverse reactions or quality issues, contact Amneal at:

**AMNEAL PHARMACEUTICALS DRUG SAFETY DEPARTMENT**

Phone: 1(877) 835-5472

Email: [Drugsafety@amneal.com](mailto:Drugsafety@amneal.com)

Mail: Amneal Pharmaceuticals, 50 Horseblock Road, Brookhaven, New York 11719

Please note that adverse events 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**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular mail or fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 (1-800-332-0178).

Thank you in advance for your cooperation.



Candis Edwards  
SVP, Regulatory Affairs  
Amneal Pharmaceuticals  
50 Horseblock Road  
Brookhaven, New York 11788  
Office: 631.952.0214 X 338  
Email: [cedwards@amneal.com](mailto:cedwards@amneal.com)



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**Impax Laboratories, LLC**  
**Epinephrine Injection, USP Auto-Injector 0.3 mg**

**PRODUCT SAFETY ADVISORY**

Epinephrine Injection, USP Auto-Injector 0.3 mg may be missing its yellow “stop collar,” potentially causing medication overdose.

**Visual inspection instructions - Affected Lots**  
**NDC# 0115-1694-30 (case) and 0115-1694-49 (carton)**

<b>Epinephrine Injection, USP Auto-Injector 0.3 mg</b>			
<b>Lot number</b>	<b>Expiration date</b>	<b>Lot number</b>	<b>Expiration date</b>
G181203X	July 2020	G190901X	December 2020
G190302X	July 2020	G190902X	January 2021
G190303X	June 2020	G190903X	January 2021
G190304X	September 2020	G190904X	February 2021
G190305X	September 2020	G190905X	February 2021
G190306X	October 2020	G190906X	February 2021
G190307X	July 2020	G190907X	February 2021
G190401X	October 2020	G191003X	February 2021
G190402X	October 2020	G191004X	February 2021
G190403X	July 2020	G191005X	February 2021
G190501X	July 2020	G191006X	February 2021
G190502X	July 2020	G191007X	April 2021
G190503X	July 2020	G191008X	April 2021
G190504X	October 2020	G191009X	April 2021
G190505X	November 2020	G191101X	February 2021
G190506X	November 2020	G191104X	April 2021
G190601X	November 2020	G191105X	April 2021
G190602X	November 2020	G191106X	April 2021
G190603X	July 2020	G191107X	May 2021
G190604X	July 2020	G191108X	May 2021
G190607X	November 2020	G191201X	April 2021
G190701X	October 2020	G191202X	April 2021
G190702X	November 2020	G191203X	April 2021
G190703X	November 2020	G191204X	May 2021
G190704X	November 2020	G191205X	May 2021
G190707X	December 2020	G191206X	May 2021
G190801X	February 2021	G200101X	May 2021
G190802X	October 2020	G200102X	May 2021
G190803X	October 2020	G200103X	May 2021
G190806X	December 2020	G200108X	February 2021