



November 01, 2018

Important Prescribing Information

Subject: Notice of Precautionary Handling Instructions for certain EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and their authorized generic versions of these strengths to confirm auto-injectors easily slide out of their carrier tube.

Dear Health Care Provider,

The purpose of this letter is to inform you that in a very small number of cases, some EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and their authorized generic versions, may not easily slide out of their carrier tube, which could delay or potentially prevent use of the device during an emergency.

EpiPen and EpiPen Jr contain epinephrine, a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

Risk That Some Auto-Injectors May Not Easily Slide Out of the Carrier Tube

- In a very small number of cases, labels were not fully adhered to the surface of the auto-injector such that the device label may become stuck to the inside of the carrier tube.
- The probability of an auto-injector having a label that is not fully adhered is very low (approximately one auto-injector out of every 14,286 or 0.007%).
- Although these are rare instances, delay in administration of EpiPen®, EpiPen Jr® and the authorized generic versions of these strengths, has a possibility of being associated with progression to a more severe allergic reaction.
- The issue is with the device label, and not with the device itself or the drug it delivers, epinephrine.
- The lifted label defect has been discussed with the U.S. Food and Drug Administration (FDA).

The root cause of this issue has been identified and corrective and preventative actions are in place.

Special Handling Instructions for HealthCare Providers

- Prior to dispensing EpiPen®, EpiPen Jr® and the authorized generic versions of these strengths to the patient, ensure that the product can be easily removed from the carrier tube. If an auto-injector does not readily slide out of the carrier tube *OR* the label is not fully adhered to the auto-injector, the auto-injector should *NOT* be dispensed.
- Additionally, once the product is about to be dispensed, counsel the patients to confirm that their auto-injector can be easily removed from the carrier tube **prior to** actual usage of the drug. Patients need to be instructed that the auto-injector can still be used when the drug is returned to the carrier tube after inspection.



- Pfizer and Mylan are providing precautionary handling instructions to provide greater assurance the auto-injectors easily slide out of the carrier tube. The detailed Precautionary Handling Instructions, including pictures of the auto-injector, are found in Appendix 1 for Health Care Providers and Appendix 2 for Consumers

This letter is being issued with the knowledge of the FDA. FDA is issuing a public advisory providing similar guidance to consumers.

AFFECTED PRODUCT

- EpiPen® 0.3 mg (EpiPen® NDC 49502-500-02) (Authorized Generic NDC 49502-102-02) products with the labeled expiry on the device and carton between June 2018 and February 2020.
- EpiPen Jr® 0.15 mg (EpiPen Jr® NDC 49502-501-02) (Authorized Generic NDC 49502-101-02) products with the labeled expiry on the device and carton between October 2018 and October 2019.

CONTACT AND REPORTING INFORMATION

Please contact Mylan Customer Relations at 1-800-796-9526 (Mon.-Friday 8 a.m. - 7 p.m. ET) for any questions you may have regarding this notification.

To report adverse reactions or quality issues, contact Mylan at 1-877-4InfoRx (1-877-446-3679).

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, phone, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail, phone, 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 (1-800-332-0178)

This letter is not intended as a complete description of the benefits and risks related to the use of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths. Full Prescribing Information is available at www.epipen.com.

We understand the challenge and inconvenience that this may pose and thank you for your attention to this important matter.

Sincerely,

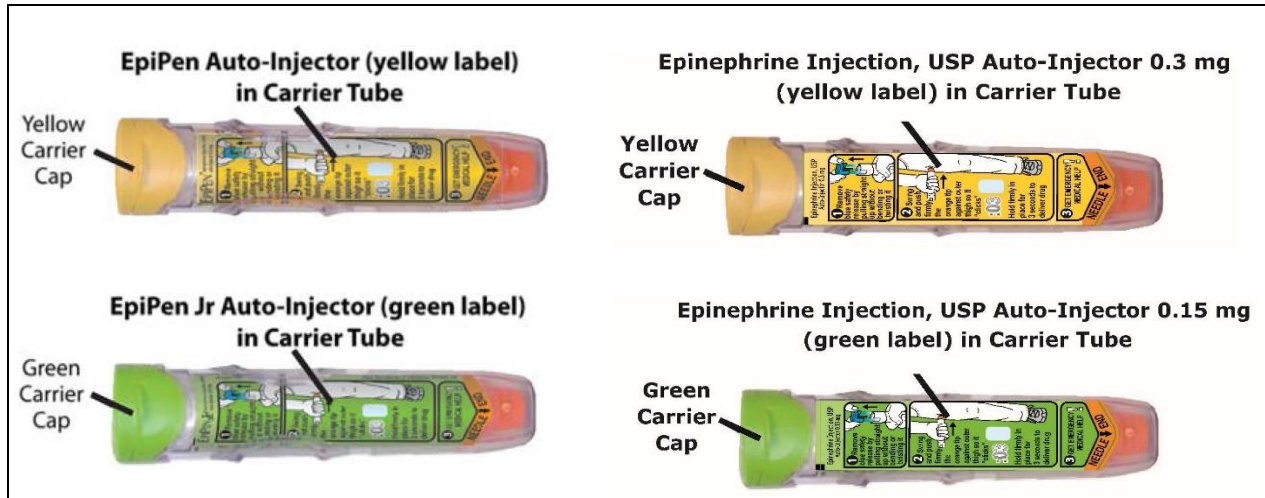
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Appendix 1: Precautionary Handling Instructions for Health Care Provider Verifying EpiPen® Auto-Injectors for Ease of Removal from Carrier Tube

EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, inside the carrier tubes are shown below in Figure 1.

Figure 1. Auto-Injectors in the Carrier Tubes



Before dispensing EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, open the carton and remove both carrier tubes containing auto-injectors from the carton. Leave all other contents inside the carton (i.e., package inserts and auto-injector trainer).

1. Check the expiry date. This issue may affect EpiPen® 0.3 mg (NDC 49502-500-02) and the Authorized Generic (NDC 49502-102-02) products expiring between June 2018 and February 2020 and EpiPen Jr® 0.15 mg (NDC 49502-501-02) and the Authorized Generic (NDC 49502-101-02) products expiring between October 2018 and October 2019.



2. Remove both carrier tubes from the S-clip.

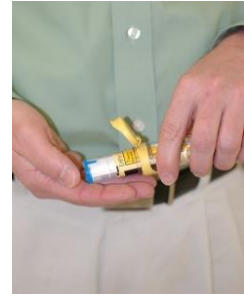
3. Per the Instructions for Use, flip open the caps of the carrier tubes. The carrier tube caps are:
 - a. yellow for EpiPen® or Epinephrine 0.3 mg, and
 - b. green for EpiPen Jr® or Epinephrine 0.15 mg.



4. Tip each carrier tube and verify that each auto-injector readily slides out of the tube. Visually inspect both auto-injectors to confirm each label is fully adhered to the auto-injector.

Do *NOT* remove the blue safety release from the auto-injector. The blue safety release should be kept on the auto-injector until the time of use.

Do *NOT* attempt to remove or re-attach your labels under any circumstances.



5. If both auto-injectors readily slide from the carrier tube *AND* the label is fully adhered to both auto-injectors:
- place both auto-injectors back into the carrier tubes,
 - close both carrier tube caps,
 - connect both carrier tubes to the S-clip, and
 - place both auto-injectors back into the carton.

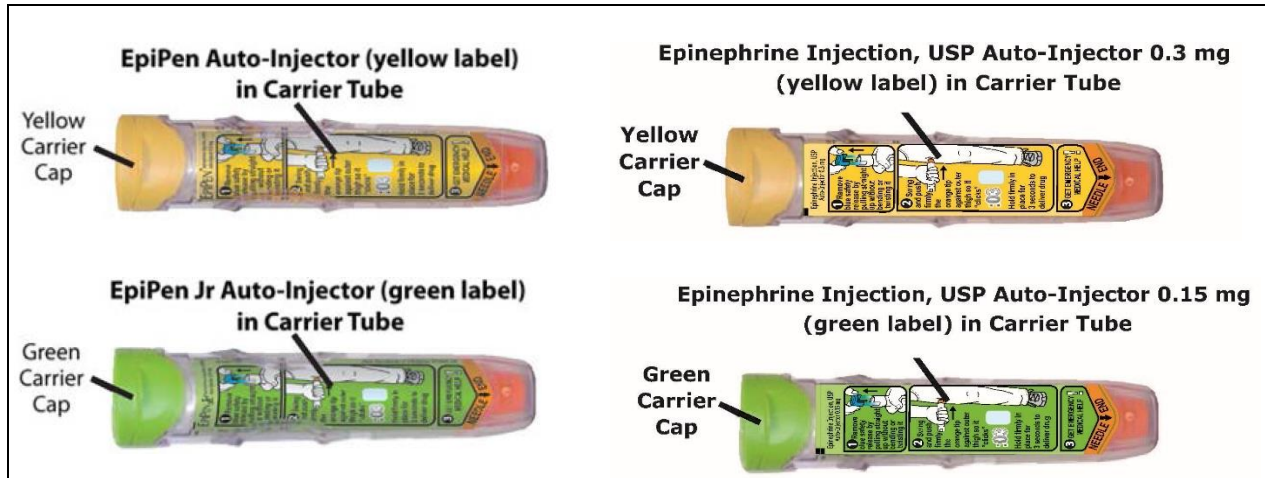
Ensure all contents (both carrier tubes each containing an auto-injector, S-clip connecting the carrier tubes, package inserts and auto-injector trainer) are placed back inside the carton and close the carton. These auto-injectors may be dispensed.

6. If an auto-injector does not readily slide out of the carrier tube *OR* the label is not fully adhered to the auto-injector, the auto-injector should *NOT* be dispensed, contact Mylan Customer Relations at 1-800-796-9526 to obtain a replacement device.

Appendix 2: Precautionary Handling Instructions for Consumers Verifying EpiPen® Auto-Injectors for Ease of Removal from Carrier Tube

EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, inside the carrier tubes are shown below in Figure 2.

Figure 2. Auto-Injectors in the Carrier Tubes



Follow these instructions *BEFORE* you may need to use your EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, to verify that your auto-injector slides readily from the carrier tube.

1. Check the expiry date. This issue may affect EpiPen® 0.3 mg (NDC 49502-500-02) and the Authorized Generic (NDC 49502-102-02) products expiring between June 2018 and February 2020 and EpiPen Jr® 0.15 mg (NDC 49502-501-02) and the Authorized Generic (NDC 49502-101-02) products expiring between October 2018 and October 2019.



2. Remove both carrier tubes from the S-clip.

3. Per the Instructions for Use, flip open the caps of the carrier tubes. The carrier tube caps are:

- a. yellow for EpiPen® or Epinephrine 0.3 mg, and
- b. green for EpiPen Jr® or Epinephrine 0.15 mg.



4. Tip each carrier tube and verify that each auto-injector readily slides out of the tube. Visually inspect both auto-injectors to confirm each label is fully adhered to the auto-injector.

Do *NOT* remove the blue safety release from the auto-injector. Keep the blue safety release on the auto-injector until time of use.

Do *NOT* attempt to remove or re-attach your labels under any circumstances.



5. If both auto-injectors readily slide from the carrier tube AND the label is fully adhered to both auto-injectors, place your auto-injectors back inside their carrier tubes. Always keep your auto-injectors in the carrier tubes to protect them from damage. These auto-injectors may be used.

6. If an auto-injector does not slide out easily from the carrier tube *OR* the label is not fully adhered to the auto-injector, contact Mylan Customer Relations at 1-800-796-9526 to obtain a replacement device.