



October 11, 2019

Subject: Important Safety Information on EpiPen® and EpiPen Jr® auto-injectors: A very rare occurrence (0.0002%) of EpiPen® and EpiPen Jr® auto-injectors not easily sliding out of the plastic carrier tube. Consumers and Pharmacists need to check their device now to confirm that it can be removed from the plastic carrier tube with ease.

Dear Healthcare Professionals,

Issue

Pfizer Canada has advised Health Canada of very rare occurrences of EpiPen® (0.3 mg) and EpiPen Jr® (0.15 mg) auto-injector devices not easily sliding out of their plastic carrier tube. The number of EpiPen® or EpiPen Jr® auto-injectors which may have a defect that could cause a delay in release from the plastic carrier tube is estimated to be 2 auto-injectors out of every 1 million (0.0002%). Delayed or no treatment could lead to worsened patient condition, including possible fatal outcome.

In a very limited number of observations (estimated 2 out of every 1 million units), a deformation on the open rim of the plastic carrier tube may be present. This defect may result in the device not sliding out of the tube as easily as expected. The issue is with the plastic carrier tube, and not with the device itself or the drug it delivers (epinephrine). This issue may affect any EpiPen auto-injectors currently on the market in Canada expiring prior to and including September 2020. The root cause of this issue has been identified and corrective and preventative actions are in place.

EpiPen® and EpiPen Jr® are used to deliver an emergency treatment of adrenaline (epinephrine) to patients who are at risk or have a history of life-threatening allergic reactions (anaphylaxis).

Health Canada is issuing a public advisory providing similar guidance to consumers.

Who is affected

- Patients and caregivers who have the affected product
- Health care providers dispensing the affected product

Affected product

- EpiPen® (0.3 mg) (DIN 00509558) and EpiPen Jr® (0.15 mg) (DIN 00578657) products expiring prior to and including September 2020

Information for Healthcare Professionals and Consumers

Information for Healthcare Professionals

Before dispensing the EpiPen® or EpiPen Jr® Auto-Injectors expiring prior to and including September 2020, flip open the cap of the plastic carrier tube and carefully ensure that the auto-injector easily slides out of the plastic carrier tube. The detailed directions, including pictures of the auto-injector, are found in Appendix 1 for Health Care Professionals.

Information for consumers

If the EpiPen® or EpiPen Jr® Auto-Injector expires prior to and including September 2020, consumers should check their device now by flipping open the cap of the plastic carrier tube and carefully ensuring that the auto-injector easily slides out of the plastic carrier tube. The detailed directions, including pictures of the auto-injector, are found in Appendix 2 for Consumers.

Information for pharmacists

When a consumer returns a unit which does not easily slide out of the plastic carrier tube, please follow the process below:

- Check the unit as per the instructions in Appendix 1
- Replace the affected EpiPen® 0.3 mg and/or EpiPen Jr® 0.15 mg for the consumer at no charge.
- Put aside the affected EpiPen® units.
- Prepare a weekly consolidation of returns by filling out the attached form and return (collect) through Purolator to MedTurn/Inmar (Purolator 0372712).

Your primary wholesaler will credit you for the affected units that you have returned at the current list price.

Correctly functioning auto-injectors will not be eligible for reimbursement or replacement.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving EpiPen® or EpiPen Jr® should be reported to Pfizer Canada ULC or Health Canada.

Pfizer Canada ULC Contact Information

17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5

Telephone: If you have an inquiry of a medical nature related to EpiPen® or EpiPen Jr®, please contact our Medical Information Group at 1-800-463-6001 (Monday – Friday 9AM-5PM). For all other inquiries, please contact our Customer Service Group at 1-800-387-4974.

To report an adverse event (or suspected side-effect) experienced with a Pfizer medication

(prescription or a vaccine) please contact Pfizer at 1-866-723-7111 or by fax at 1-855-242-5652.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

Sincerely,

A handwritten signature in blue ink, appearing to read "Vratislav Hadrava", with a long horizontal flourish extending to the right.

Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

**Appendix 1: Special Instructions for Healthcare Professionals:
Verifying EpiPen® Auto-Injectors for Ease of Removal from Plastic carrier tube**

Before dispensing EpiPen® or EpiPen Jr® auto-Injectors expiring prior to and including September 2020, open the carton and remove the plastic carrier tube containing the auto-injector from the carton. Leave the package insert inside the carton.

1. Check the expiry date.



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



3. Tip the plastic carrier tube and verify that the auto-injector readily slides out of the tube. Visually inspect the plastic carrier tube to make sure that the open rim of the plastic carrier tube is not deformed.

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.



4. Once you have confirmed that the device slides out easily and there are no deformities on the open rim of the plastic carrier tube, return the EpiPen® into its plastic carrier tube and close the plastic carrier tube flip cap. The auto-injector may be dispensed and administered when needed.
5. If the device does not slide out easily from its plastic carrier tube, or the open rim of the plastic carrier tube appears deformed, the auto-injectors should **NOT** be dispensed.

Appendix 2: Special Instructions for CONSUMERS

Verifying EpiPen® Auto-Injectors for Ease of Removal from Plastic carrier tube

In a non-emergency situation, follow these instructions to verify that your EpiPen® or EpiPen Jr® auto-injector slides easily from the plastic carrier tube.

1. Check the expiry date. This issue may affect EpiPen® auto-injectors in Canada expiring prior to and including September 2020.

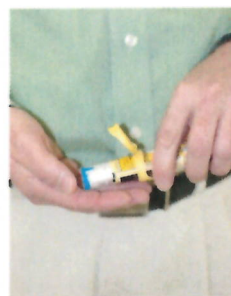


2. Per the Instructions for Use, flip open the cap of the plastic carrier tube. The plastic carrier tube caps are:
 - a. yellow for EpiPen® or Epinephrine 0.3 mg, and
 - b. green for EpiPen Jr® or Epinephrine 0.15 mg.



3. Tip the plastic carrier tube and verify that the auto-injector slides easily from the tube. Visually inspect the auto-injector to make sure the open rim of the plastic carrier tube is not deformed.

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



4. Once you have confirmed that your device slides out easily and there are no deformities on the open rim of the plastic carrier tube, return the EpiPen® into its plastic carrier tube and close the plastic carrier tube flip cap. The auto-injector may be used when needed.

Always keep your auto-injector in the plastic carrier tube to protect it from damage.

5. If the device does not slide out easily from its plastic carrier tube, or the open rim of the plastic carrier tube appears deformed, **YOU MUST RETURN IT TO YOUR PHARMACIST FOR REPLACEMENT.**

If you are unsure about how to check your device, your pharmacist can check your device for you.

PLEASE INDICATE BELOW THE EPIPEN 0.3MG AND EPIPEN JR 0.15 MG INVENTORY OF THE LOTS WITH PLASTIC CARRIER TUBE ISSUE WHICH YOU ARE RETURNING							
DIN	PRODUCT CODE	PRODUCT DESCRIPTION	SIZE	UPC	LOT #	EXPIRY DATE	UNITS RETURNED
00509558	00121	Solution, 0.3 mg	Auto-Injector	625813 001213			
00578657	00111	Solution, 0.15 mg	Auto-Injector	625813 001114			
PLEASE COMPLETE THE FORM AND SEND TO INMAR BACK WITH YOUR EPIPEN RETURN.							
Customer Name:							
Wholesaler name:							
Wholesaler account number:							
Street Address:							
City:							
Province:							
Postal Code:							

Name of Authorised Person	Signature	Date

Please return all units of product identified above as well as a copy of this form by Purolator Collect (0372712) and waybill sender reference **PC101119** on the waybill to the following address:

Inmar MedTurn
 50 Dynamic Drive,
 Toronto, ON
 M1V 2W2
 Canada