

Health Canada Endorsed Important Information on
the Correct Use of EpiPen® and EpiPen® Jr Auto-Injector



December 22, 2011

Dear Healthcare Professional:

Subject: Important Safety Information on the Correct Use of EpiPen® and EpiPen® Jr Auto-Injector

Pfizer Canada Inc. (distributor of EpiPen for Dey Pharma, L.P.) in collaboration with Health Canada would like to advise you of the correct method to remove the blue safety release and of the importance of following the instructions for use of EpiPen (0.3 mg epinephrine auto-injector) and EpiPen Jr (0.15 mg epinephrine auto-injector). It has recently come to our attention that removal of the blue safety release the wrong way, by pulling it sideways or bending and twisting it off (in a manner inconsistent with the current product labelling), may cause the auto-injector to spontaneously activate or not work correctly, resulting in failure to deliver the drug.

- Your patients should continue to carry their EpiPen or EpiPen Jr at all times and we encourage you to review the information below with your patients and their caregivers to ensure its appropriate use.
- Patients and their caregivers should be advised that the blue safety release should be removed by pulling straight up.
- The blue safety release should NOT be removed by pulling it sideways or bending and twisting as this may prevent the device from working properly and result in failure to deliver the drug.

EpiPen and EpiPen Jr are indicated for the emergency treatment of anaphylactic reactions in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

When using EpiPen or EpiPen Jr Auto-injector, patients and their caregivers are reminded to follow the instructions outlined below:

Remove EpiPen® Auto-injector from carrier tube



- Hold firmly with orange tip pointing downward
- Remove blue safety cap by pulling straight up (*Do not bend or twist the blue safety cap*)



- Swing and push orange tip firmly into mid-outer thigh until you hear a 'click'
- Hold on thigh for several seconds

It is recommended that you do a hands-on demonstration using the training device with your patients of the proper administration technique. Patients and their caregivers should be advised that the blue safety release should be removed straight up. It should NOT be removed by pulling it sideways or bending and twisting as this may prevent the device from working properly and result in failure to deliver the drug.

Patients and their caregivers should be advised to periodically review the instructions that accompany the product to ensure they know how to use the device correctly and to verify that it has not unintentionally activated. Training materials including DVDs and EpiPen training devices which teach people how to use the device can be ordered free of charge at www.EpiPen.ca or by phone at 1-877-EPIPEN1 (1-877-374-7361).

Pfizer Canada Inc. is working on measures to further educate patients on the appropriate use of EpiPen and EpiPen Jr.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any malfunction or serious or unexpected adverse reactions in patients receiving EpiPen or EpiPen Jr should be reported to Pfizer Canada Inc. or Health Canada.

Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
Telephone: 1-800-463-6001

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](#) section.

<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

For other health product inquiries related to this communication, please contact Health Canada at:

Health Product and Food Branch Inspectorate (HPFBI)
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

Should you have any questions on the use of EpiPen or EpiPen Jr, please contact Pfizer Canada at the address or telephone listed above or call 1-877-EPIPEN1 (1-877-374-7361).

A handwritten signature in black ink, appearing to read "B. Prigent". The signature is written in a cursive style with a long, sweeping horizontal line extending from the end of the name.

Bernard Prigent, MD, MBA
Vice-President and Medical Director
Pfizer Canada Inc.