

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



December 22, 2011

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 remind patients of the correct method to remove the blue safety cap 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 cap the wrong way by pulling it sideways or bending and twisting it off may prevent the device from working properly and potentially result in failure to deliver the drug.

- Patients should continue to carry their EpiPen or EpiPen Jr at all times and are encouraged to review the information below to ensure its appropriate use.
- The blue safety cap should not be removed until you need to use the EpiPen or EpiPen Jr.
- When the blue safety cap is removed from the EpiPen or EpiPen Jr, it is important that it is removed by pulling it straight up. Do not bend or twist the blue safety cap.

EpiPen is a pre-filled, single-use automatic injector containing an epinephrine solution that is used for the emergency treatment of severe allergic reactions, including anaphylaxis. The product is available in two dosing strengths, 0.3 mg and 0.15 mg.

When using EpiPen or EpiPen Jr Auto-injector, patients 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

The blue safety cap should not be removed until you need to use the EpiPen or EpiPen Jr. When the blue safety cap is removed from the EpiPen or EpiPen Jr, it is important that it is removed by pulling it straight up. The blue safety cap should NOT be removed by pulling it sideways or bending and twisting. Inappropriate removal of the blue safety cap may prevent the device from working properly and potentially result in failure to deliver the drug.

From time to time, patients should read the instructions for how to use the EpiPen or EpiPen Jr. and check 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).

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 horizontal stroke extending to the right.

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