

To: Z029429 (2504794200) HEAD NURSE; ROYAL OAK MIDDLE SCHOOL (P7662F)
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June 13, 2015

Voluntary Product Recall: Allerject 0.15 mg / 0.1 mL epinephrine injection

Dear stakeholder,

On Friday, June 12, 2015 Sanofi Canada took the precautionary measure of issuing a Voluntary Recall of Allerject 0.15 mg / 0.15 mL epinephrine auto injectors, lots 2857505 and 2857508, due to a manufacturing defect that could potentially affect the delivery of the drug. These auto injectors became available in the Canadian market for distribution as of June 1st, 2015. The defect was discovered as part of a routine manufacturer quality review process. Allerject 0.15 mg / 0.15 mL is the pediatric version of the epinephrine auto injector. No other lots or strengths of Allerject, or any other Sanofi Canada products are included in this recall. There have been no reports of patients adversely affected by the two lots distributed to date.

Patient safety is our top priority and Sanofi Canada is communicating to stakeholders involved in management of patients and consumers with anaphylaxis including contacting healthcare practitioners, retail pharmacists and hospitals to inform them of this precautionary recall. We are informing the public that should they be in possession of an affected product, they should immediately return the product to their local pharmacy for replacement.

Health Canada has issued a communications relating to the recall. [Link](#). To ensure the safety of children at risk of anaphylaxis we would ask for your assistance to ensure that any individual who may be in possession of an auto-injector impacted by this recall (lots 2857505 and 2857508) is immediately made aware.

Patients with questions or concerns should contact the Allerject Call Center at 1-855-405-4321. Customers with questions relating to logistics should contact Sanofi Customer Service at 1-800-265-7927.

Thank you for your support in helping us communicate this matter. The safety of our patients is our highest priority.

sanofi-aventis Canada Inc.



PRODUCT IDENTIFICATION			
Name	French: Allerject 0.15 mg / 0.15 mL epinephrine injection English: Allerject 0.15 mg / 0.15 mL epinephrine injection		
UPC	065914 11216 4 065914 11217 1		
DIN/NPN/Device	02382059		
Lot(s)	2857505 (French)	Expiry	Sep 2016
	2857508 (English)		Sep 2016

Note that other lots are NOT affected by this recall

Sincerely,

Vice-President, Medical and Regulatory Affairs
Sanofi Canada