

Nationwide Voluntary Recall of Allerject®

ADDITIONAL INFORMATION

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What should Canadian consumers do if they have Allerject?

Canadian customers are instructed to immediately return all Allerject devices to their local pharmacy.

Previous recommendations to limit the number of devices that can be replaced for an alternate auto-injector are now removed as a result of the announcement that supply an alternative product is sufficient to satisfy the demand.

All Allerject epinephrine auto-injectors returned by patients to their pharmacist with an expiry date between October 2015 and December 2016 inclusively continue to be eligible for replacement at no cost to the patient.

If you have additional questions about this recall, you can contact the Allerject Call Center at 1 855-405-4321. If your pharmacist has specific questions relating to product return logistics, they should contact Sanofi Customer Service at 1-800-265-7927.

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Is a prescription required to receive a replacement for my Allerject?

No prescription is required to receive a replacement epinephrine auto-injector.

Will patients have to pay for their replacement medication?

Sanofi is collaborating with retail pharmacy chains and pharmacists to ensure patients receive an alternate device at no cost to the patient.

What drug can be substituted as the replacement for Allerject?

EpiPen is the only epinephrine auto-injector currently available in Canada.*

*Twinject and Anapen are approved in Canada but not currently marketed.

You say this is a voluntary recall, but did Health Canada advise you to recall Allerject?

During a routine manufacturing quality review, issues with the Allerject device were discovered at a contract manufacturer that may potentially affect the delivery of the required amount of drug. As a precautionary measure and with the knowledge of Health Canada and the FDA, Sanofi issued a voluntary Type I (Class I in the US) recall of all Allerject and Auvi-Q.

Have you alerted healthcare professionals?

Yes, we are actively communicating with healthcare professionals.

What should a patient do if the Allerject product they have fails to work?

Call 911 and immediately seek emergency medical services, in accordance with current product labelling. Any event that may be related to the use of this product should be reported either to Sanofi Canada or to MedEffect Canada's website.

What is the potential or theoretical risk if the recalled product is administered to patients?

There is no risk associated with the drug itself, but there is an issue with the device that may potentially affect delivery of the required amount of epinephrine. If a patient experiencing a serious allergic reaction (i.e. anaphylaxis) did not receive the intended dose, there could be significant health consequences, including death because anaphylaxis is a potentially life threatening condition

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Are there plans to bring Allerject back to the Canadian market?

While we cannot speak on behalf of kaléo, they have discussed with Sanofi that they will evaluate timing and options for bringing Allerject back to market. Please contact kaléo with any questions about their plans.

Does this announcement have any impact on the Allerject voluntary recall process announced October 28, 2015?

No. Sanofi Canada continues to ensure the completion of the return and replacement process associated with the October 28, 2015 voluntary nationwide product recall of Allerject. Canadian customers are instructed to immediately return all Allerject devices to their local pharmacy. All Allerject epinephrine auto-injectors returned by patients to their pharmacists with an expiry date between October 2015 and January 2017 inclusively continue to be eligible for replacement with an alternative epinephrine auto-injector at no cost to the patient.

Sanofi Canada continues to communicate with wholesalers, pharmacists, patients and caregivers, patient associations and hospitals to keep them informed.

For more information regarding the voluntary recall, please refer to the press release issued on December 2, 2015.