



For Canadian media only

Update by Sanofi Canada on Nationwide Voluntary Recall of Allerject®

FOR IMMEDIATE RELEASE

Laval, Quebec – December 2, 2015 – Following the October 28, 2015 voluntary recall by Sanofi-aventis Canada Inc. (Sanofi Canada) of all lots of Allerject® epinephrine auto-injectors of both the 0.15mg/0.15mL and 0.30mg/0.3mL strengths, and given the recent announcement that stock of alternative epinephrine auto-injectors is now sufficient to replace all Allerject® devices in Canada, Sanofi Canada is notifying the public of the following updates:

- **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 of the 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.**

As a reminder, Sanofi Canada voluntarily recalled all Allerject® devices as they were found to potentially have inaccurate dosage delivery. If a patient who is 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.

Sanofi Canada is committed to patient safety.

We are proactively communicating with wholesalers, pharmacists, patients and caregivers, patient associations, and hospitals to inform them of this new information.

Allerject® (epinephrine injection, USP) is used to treat life-threatening allergic reactions (anaphylaxis) in people who are at risk for or have a history of these reactions. All Allerject® units are being recalled.



For questions or concerns about the voluntary recall, please contact:

- Allerject® Call Center at 1-855-405-4321.



Any adverse events that may be related to the use of these products should continue to be reported either to:

- Sanofi Canada
Phone: 1-855-405-4321
- Health Canada
Phone: 1-866-234-2345
- MedEffect Canada website:
<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

Important Safety Information

Indication

Allerject® is 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.

Important Safety Information

Allerject® is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use. Each Allerject® contains a single dose of epinephrine. **Allerject® should only be injected into your outer thigh. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY.** If you accidentally inject Allerject® into any other part of your body, seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

If you take certain medicines, you may develop serious life-threatening side effects from epinephrine. Be sure to tell your doctor about all the medicines you take, especially medicines for asthma. Side effects may be increased in patients with certain medical conditions, or who take certain medicines. These include asthma, allergies, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure, and heart disease.

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These side effects go away quickly, especially if you rest.

You are encouraged to report negative side effects of prescription drugs. In Canada, please call 1-866-234-2345 or visit <http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>.

Please click [here](#) (Canada) for Full Prescribing Information.

About Sanofi – www.sanofi.ca

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi entities in Canada include Sanofi Canada (pharmaceuticals), Sanofi Pasteur (vaccines), Sanofi Consumer Health (cosmeceuticals, over-the-counter products and specialty care), Genzyme (rare diseases) and Merial (animal health). Together they employ close to 1,700 people. In 2014 Sanofi companies invested \$130.5 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

Follow Sanofi Canada on Twitter @SanofiCanada and on YouTube [youtube.com/user/sanoficanada](https://www.youtube.com/user/sanoficanada).

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