

## All EMERADE® epinephrine auto-injectors in Canada recalled

- *If you have an unexpired EMERADE auto-injector return it to your pharmacy*
- *Voluntary recall by Bausch Health, Canada with Health Canada*

Bausch Health, Canada Inc. has announced it is conducting a voluntary recall of all inventory of **EMERADE® Sterile Epinephrine Injection**, including those in the hands of patients.

If you have unexpired EMERADE epinephrine auto-injectors, return them to your pharmacy as soon as possible.

There are other epinephrine auto-injectors available through pharmacies across Canada.

EMERADE Sterile Epinephrine Injection is indicated for the emergency treatment of severe allergic reactions (anaphylaxis) triggered by allergens in foods, medicines, insect stings or bites, and other allergens and for exercise-induced or idiopathic anaphylaxis.<sup>1</sup>

Bausch Health, Canada chose to initiate this voluntary action due to the potential risk that the auto-injector may fail to activate or activate prematurely if dropped. The decision to conduct this voluntary recall is part of our ongoing commitment to ensuring all our products meet the highest standards of quality. We take matters such as this very seriously, which is why we are taking this recall action.

The company has informed Health Canada about this action and is implementing their recommended recall protocols.

Communications have been issued to wholesalers and pharmacists across Canada to immediately stop all sales of EMERADE and information about this recall has also been communicated to doctors.

If you have questions about this voluntary recall or would like additional information, please contact Bausch Health, Canada Inc. Customer Service at 1-800-361-4261.

### Questions and Answers about the EMERADE® recall

#### What is EMERADE used for?

EMERADE® is used for the emergency treatment of a sudden, severe, and life-threatening allergic reaction. This type of severe reaction is called anaphylaxis. EMERADE is used in people:

- who are at a higher risk for severe allergic reactions
- with a history of allergic reactions

It is used to treat people with severe allergies to:

- foods like peanuts, tree nuts, shellfish, fish, milk, eggs and wheat
- insect stings like those from bees, wasps, hornets, yellow jackets and fire ants
- insect bites like those from mosquitos and black flies

- certain medicines
- latex
- other allergens (a substance that causes allergies)

These severe allergic reactions can also be caused by exercise, asthma or by unknown causes.<sup>1</sup>

### **Why is Emerade being recalled?**

The company has chosen to initiate this voluntary action due to the potential risk that the auto-injector may fail to activate or activate prematurely if dropped. This decision is part of the company's ongoing commitment to ensuring all of its products meet the highest standards of quality. Bausch Health, Canada takes matters such as this very seriously, which is why this action has been taken promptly after coming to light.

### **How serious is this issue?**

A risk to the patient's health cannot be excluded. Failure to activate is evaluated as life-threatening, which is why Bausch Health has voluntarily decided to make this recall, to the patient level, meaning patients with EMERADE should return it to their pharmacy.

### **How serious is the probability of this problem causing EMERADE not to work when it is needed in a potentially life-threatening situation?**

We don't believe the probability is high but are taking this action to protect Canadians who have EMERADE and might need to use it.

### **Is someone who has recently successfully used an Emerade device because of an anaphylactic reaction in any danger or risk of health effects?**

No, the potential risk is that when Emerade is dropped and will be needed by someone having an anaphylactic reaction that the device might not activate and not deliver the epinephrine dose.

### **What part of the EMERADE inventory is affected?**

This affects all non-expired inventory of EMERADE in Canada. Bausch Health, Canada has asked wholesalers and pharmacists to immediately stop all sales of Emerade. Individuals in possession of non-expired EMERADE auto-injectors should return them to their pharmacy.

### **Are you working with Health Canada on this recall?**

Health Canada has been fully informed in accordance with the required procedures for drug recalls in Canada.

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<sup>1</sup> Bausch Health, Canada, EMERADE® Product Monograph, November 28, 2002

**What alternatives are available for those who need an epinephrine auto-injector?**

There are other epinephrine auto-injectors available through pharmacies across Canada.

**What should patients do?**

There are other epinephrine auto-injectors available through pharmacies across Canada. The patient should speak with their doctor to determine which epinephrine auto-injector is right for them.

If the patient is not seeking public or private insurance coverage for their epinephrine auto-injector, they can acquire a different type of auto-injector directly from the pharmacy. However, if they have public or private insurance coverage, they will require a new prescription from their doctor for a different replacement.

**Do you know when the issue will be resolved and EMERADE will be available again?**

Our priority at present is to focus on the recall. Therefore, we cannot comment on availability at this time.

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<sup>i</sup> Emerade Product Monograph, November 28, 2022