

# Symjepi® (epinephrine) Injection Recall Alert

Date of Notice: March 22, 2022

### **Brief Description of Recall Alert**

Adamis Pharmaceuticals Corporation is voluntarily recalling certain lots of Symjepi® (epinephrine) injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) pre-filled single-dose syringes. The batches are being recalled due to the potential clogging of the needle, preventing the dispensing of epinephrine.

If a person is experiencing an allergic reaction and/or anaphylaxis and is unable to access life-saving epinephrine due to the syringe malfunction, it can lead to life threatening consequences including death.

## **Affected Products**

Drug Name & Strength	NDC	Lot	Expiration Date
Symjepi (epinephrine) Injection, 0.15 mg/0.3 mL	78670-131-02	21101Y	11/30/2022
Symjepi (epinephrine) Injection, 0.3 mg/0.3 mL	78670-130-02	21041W	8/31/2022
		21081W	11/30/2022
		21102W	2/28/2023

## **Prescriber Information**

US WorldMeds is notifying its customers by email, FDA alerts, and direct outreach. Consumers and institutions that have product that are subject to this recall should stop using the product immediately and may either return or discard the recalled lots. Although not confirmed to be related to the recall, there have been two different customer complaints on three syringes, regarding difficulty in dispensing the product, to date. However, neither USWM nor Adamis Pharmaceuticals has received, or is aware of, any adverse events related to this recall.

For questions regarding this recall, use the appropriate Adamis Pharmaceutical Corporation contact information below:

#### **Quality Compliance**

Craig Stenland
 Quality Compliance Partners
 858-361-6456
 craigs@qualpartners.com

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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#### **Investor Relations**

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Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: <u>Download form</u> or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

### **Member Information**

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the products being recalled, should contact US WorldMeds by phone, (888) 900-8796, or e-mail questions to medinfo@usworldmeds.com Monday-Friday from 8:00 am to 4:00 pm ET.

# **RxAdvance Response**

Members should continue using Symjepi® until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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