Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-037-CG
March 23, 2022

FDA announced that, Adamis Pharmaceuticals CorporationExternal Link Disclaimer (Nasdaq: ADMP) 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 to the consumer level. The batches included in this notice are being recalled due to the potential clogging of the needle preventing the dispensing of epinephrine. US WorldMeds (USWM) exclusively markets and distributes SYMJEPI in the United States, under license from Adamis, the NDA holder. USWM will handle the entire recall process for Adamis, with Adamis oversight. SYMJEPI is manufactured and tested for Adamis by Catalent Belgium S.A.

RECOMMENDATIONS

1. US WorldMeds is notifying its customers by email, FDA alerts, and direct outreach.
2. Consumers and institutions that have products that are subject to this recall should stop using the products immediately and may either return or discard the recalled lots.
3. Consumers with questions regarding this recall can call **(888) 900-8796** or e-mail questions at medinfo@usworldmeds.com Monday-Friday from 8:00 am to 4:00 pm ET.
4. Review your inventory to identify existence of recalled products.
5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Call Box 4908, Caguas, PR 00726

FDA U.S. FOOD & DRUG ADMINISTRATION

Adamis Pharmaceuticals Corporation Issues Nationwide Voluntary Recall of SYMJEPI® (Epinephrine) Injection for Potential Manufacturing Defect

Summary:

Company Announcement Date:	**March 21, 2022**
FDA Publish Date:	**March 22, 2022**
Product Type:	**Drugs**
Reason for Announcement:	**Potential clogging of the needle preventing the dispensing of epinephrine**
Company Name:	**Adamis Pharmaceuticals Corporation**
Brand Name:	**Adamis Pharmaceuticals Corporation**
Product Description:	**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**

Company Announcement

San Diego, March 21, 2022 – Adamis Pharmaceuticals CorporationExternal Link Disclaimer (Nasdaq: ADMP) 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 to the consumer level. The batches in the table below are being recalled due to the potential clogging of the needle preventing the dispensing of epinephrine. US WorldMeds (USWM) exclusively markets and distributes SYMJEPI in the United States, under license from Adamis, the NDA holder. USWM will handle the entire recall process for Adamis, with Adamis oversight. SYMJEPI is manufactured and tested for Adamis by Catalent Belgium S.A.

Risk Statement:

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. 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 US WorldMeds nor Adamis Pharmaceuticals has received, or is aware of, any adverse events related to this recall.

FDA U.S. FOOD & DRUG ADMINISTRATION

The recall encompasses all of the following batches, within expiry:

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

SYMJEPI is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

The products are packaged in 2-count Pre-Filled Single-Dose Syringes per carton and were distributed nationwide in the USA and directly to customers and/or medical facilities. The products can be identified by the label containing the US WorldMeds name and logo pictured in the following link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamis-pharmaceuticals-corporation-issues-nationwide-voluntary-recall-symjepir-epinephrine-injection.

US WorldMeds is notifying its customers by email, FDA alerts, and direct outreach. Consumers and institutions that have products that are subject to this recall should stop using the products immediately and may either return or discard the recalled lots. Consumers with questions regarding this recall can call (888) 900-8796 or e-mail questions at medinfo@usworldmeds.com Monday-Friday from 8:00 am to 4:00 pm ET.

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: Download form 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