Adamis Issues Nationwide Voluntary Recall of Symjepi® (Epinephrine) Injection for Potential Manufacturing Defect

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Adamis Pharmaceuticals Corporation is voluntarily recalling certain lots of Symjepi (epinephrine) Injection (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) prefilled 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 (US), under license from Adamis, the New Drug Application (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.

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

Product	Strength	NDC	Lot	Expiration
Symjepi (epinephrine) Injection	0.15 mg/0.3 mL	78670-0131-02	21101Y	11/30/2022
	0.3 mg/0.3 mL	78670-0130-02	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 prefilled single-dose syringes per carton and were distributed nationwide in the US and directly to customers and/or medical facilities. The products can be identified by the label containing the US WorldMeds name and logo pictured on the cartons below.

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 through 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

This recall communication is from the FDA: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamis-pharmaceuticals-corporation-issues-nationwide-voluntary-recall-symjepir-epinephrine-injection

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Product Photos

Click here for product photos.