COMMUNICATION

COM-2022-020

URGENT PLEASE REVIEW PharmPix Clinical Department

U.S. Food & Drug Administration Publication Date:

03/22/2022

Drug Information:

National Drug Code 78670-0131-02

78670-0130-02

Product Description

Symjepi[™] (epinephrine) injection 0.15mg/0.3mL and 0.3mg/0.3mL

Lot Number

For NDC 78670-0131-02 (strength: 0.15mg/0.3mL): 21101Y

For NDC 78670-0130-02 (strength: 0.3mg/0.3mL): 21041W, 21081W, 21102W

Expiration Date Lot 21101Y: 11/30/2022

Lot 21041W: 8/31/2022

Lot 21081W: 11/30/2022

Lot 21102W: 2/28/2023

QUESTIONS

Call US WorldMeds at 888-900-8796 or e-mail questions at medinfo@usworldmeds.com

Monday – Friday from 8:00 a.m. to 4:00 p.m. ET.



PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

Symjepi™ (epinephrine)

It is for this reason that we are notifying you that on 03/22/2022, the US Food and Drug Administration published a drug recall for the following product(s): SymjepiTM injection 0.15mg (0.15mg/0.3mL) and 0.3mg (0.3mg/0.3mL) prefilled single-dose syringes.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Adamis Pharmaceuticals Corp. is voluntarily recalling certain lots of Symjepi[™] to the consumer level due to the potential clogging of the needle preventing the dispensing of epinephrine. If a person is experiencing an allergic reaction and/or anaphylaxis due to the syringe malfunction, it may lead to life threatening consequences.

The products were distributed nationwide in the USA and directly to customers and/or medical facilities. US WorldMeds is notifying its customers by email, FDA alerts, and direct outreach. 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. Neither US WorldMeds nor Adamis Pharmaceuticals has received, or is aware of, any adverse events related to this recall.



Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication COM-2022-020 April 2022





REFERENCES:

1. U.S. Food and Drug Administration. (2022). Adamis Pharmaceuticals Corporation Issues Nationwide Voluntary Recall of Symjepi (Epinephrine) Injection for Potential Manufacturing Defect.

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamis-pharmaceuticals-corporation-issues-nationwide-voluntary-recall-symiepir-epinephrine-injection 2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reportingserious-problems-fda

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