COMMUNICATION

COM-2024-021

15
MARCH
2024

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

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

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

U.S. Food & Drug Administration Publication Date:

03/12/2024

Drug Information:

National Drug Code

42023-206-01

Product Description

Treprostinil™ 20mg/20mL Injection

Lot Number

57014

Expiration Date

04/2024

Company

Endo International

Par Pharmaceutical, Inc.

QUESTIONS

Call Inmar, Inc. at 1-855-410-3565 Monday through Friday between the hours of 9 am and 5 pm EST.

Treprostinil Injection

It is for this reason that we are notifying you that on March 12, 2024 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Treprostinil™ 20mg/20mL Injection

Pharmacy Required Action

Identify if the product is in inventory 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

Par Pharmaceutical, Inc. is voluntarily recalling one lot of Treprostinil Injection 20mg/20mL (1mg/mL) to the consumer level. The product is being recalled due to the potential for the presence of silicone particulates in the product solution.

Only Lot 57014 with the expiration date 04/2024 is affected by this recall. The lot was distributed nationwide to wholesalers and hospitals from June 16, 2022, through October 17, 2022.

Administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can reach various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Par has not received any reports of adverse events related to this recall.

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

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- ext 116. 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 Number COM-2024-021 March 2024

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REFERENCES: <<APA FORMAT>>

1. U.S. Food and Drug Administration. (2024). Par Pharmaceutical Issues Voluntary Nationwide Recall of One Lot of Treprostinil Injection Due to Potential for Silicone Particulates in the Product Solution. Retrieved March 15, 2024, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/par-pharmaceutical-issues-voluntary-nationwide-recall-one-lot-treprostinil-injection-due-potential
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/reporting-serious-problems-fda

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