COMMUNICATION

COM-2024-037

30
MAY
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:

05/29/2024

Drug Information:

National Drug Code

25021-254-16

25021-254-08

Product Description

Docetaxel Injection, USP

Lot Number

F1030001

F1040001

Expiration Date

December 2024

Company:

Sagent Pharmaceuticals

QUESTIONS

Call customer call center at (866) 625-1618 M-F, 8am-5pm CST, option 1.

For medical questions call Medical Affairs (866) 625-1618, Option 3, M-F, 8am-5pm CST.

Docetaxel Injection, USP

It is for this reason that we are notifying you that on 05.30.2024 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product: Docetaxel Injection, USP (80 mg per 8 mL multi-dose vials and 160 mg per 16 mL multi-dose vials).

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:

Sagent Pharmaceuticals, Inc., is voluntarily recalling two lots of Docetaxel Injection, USP (80 mg per 8 mL multi-dose vials and 160 mg per 16 mL multi-dose vials), lot F1030001 and lot F1040001, to the user level. The recall was initiated as the result of a customer complaint due to potential presence of particulate matter from the stopper in the drug product.

Should a patient receive an injectable product containing particulate matter, it may result in inflammation of a vein, granuloma, and blockage of blood vessels in the heart, lungs or brain which can cause stroke or life-threatening blood clot events.

To date, Sagent Pharmaceuticals has not received any reports of serious adverse events related 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- ext 219. 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-2024-037 May 2024

pharmpix
POWERED BY ONEARK

REFERENCES:

1. U.S. Food and Drug Administration. (2024). Sagent Pharmaceuticals issues voluntary nationwide recall of Docetaxel Injection, USP due to potential presence of particulate matter. Retrieved from http://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sagent-pharmaceuticals-issues-voluntary-nationwide-recall-docetaxel-injection-usp-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

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025