DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Sagent Pharmaceuticals Issues Voluntary Nationwide Recall of Docetaxel Injection, USP Due to Potential Presence of Particulate Matter

05/29/2024

FOR IMMEDIATE RELEASE - SCHAUMBURG, IL – May 28, 2024 – Sagent Pharmaceuticals today announced the voluntary nationwide recall of two lots of Docetaxel Injection, USP (80 mg per 8 mL multi-dose vials and 160 mg per 16 mL multi-dose vials). The product was distributed by Sagent Pharmaceuticals. Sagent has initiated this voluntary recall of Docetaxel Injection, USP to the User Level as the result of a customer complaint due to potential presence of particulate matter from the stopper in the drug product.

Risk Statement: Intravenous administration of an injectable product that contains particulate matter may result in serious adverse events. Potential complications related to injection of particles include 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. The frequency and severity of these adverse events could vary depending upon a variety of factors including the size and number of particles in the drug product, patient comorbidities (such as age, compromised organ function), and presence or absence of vascular anomalies.

To date, Sagent Pharmaceuticals has not received any reports of adverse events related to this recall.

The Docetaxel Injection, USP, label and affected lot numbers with Expiration Dates and NDC number can be found in the table below. Product was distributed Nationwide from October 11, 2023, to April 11, 2024.

Product	Lot Number	NDC	Expiration Date	Strength
DOCETAXEL INJECTION, USP	F1030001	25021-254-16	12/2024	160 mg/16 mL (10 mg/mL)
	F1040001	25021-254-08	12/2024	80 mg/8 mL (10 mg/mL)

Customers are being notified by a FedEx package that includes arrangements for return of all recalled product. Customers are instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots listed above. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. Consumers/distributors/retailers that have product which is being recalled should stop using product and return the recalled product. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.comExternal Link Disclaimer.

Customers with any questions about returning unused product are directed to the customer call center at (866) 625-1618 M-F, 8am-5pm CST, option 1. Healthcare workers who have medical questions about Docetaxel Injection, USP, may contact Medical Affairs (866) 625-1618, Option 3, M-F, 8am-5pm CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product

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.

Company Contact Information

Consumers:

Customer Call Center

(866) 625-1618 Option 1

Product Photos:

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Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sagent-pharmaceuticals-issues-voluntary-nationwide-recall-docetaxel-injection-usp-due-potential?utm_medium=email&utm_source=govdelivery