DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Sandoz, Inc. Issues Nationwide Recall of 13 Lots of Orphenadrine Citrate 100 mg Extended-Release Tablets Due to Presence of a Nitrosamine Impurity

3/21/2022

Princeton, NJ, Sandoz Inc. ("Sandoz") is initiating a voluntary recall of 13 lots (listed below) of oral Orphenadrine Citrate 100 mg Extended Release (ER) Tablets to the consumer level. The presence of a nitrosamine (N-methyl-N-nitroso-2-[(2-methylphenyl) phenylmethoxy] ethanamine (NMOA or Nitroso-Orphenadrine)) impurity, which has the potential to be above the U.S. Food and Drug Administration (FDA)'s Acceptable Daily Intake (ADI) limit of 26.5 ng/day, was detected in the lots during recent testing. These 13 lots of Orphenadrine Citrate ER Tablets were shipped to customers from August 2019 to April 2021.

Nitrosamines are substances with carcinogenic potency (substances that could cause cancer) when present above the allowable exposure limits. While the use of product belonging to the recalled lots may represent a risk to patients, to date, Sandoz has not received any reports of adverse events related to the presence of a nitrosamine impurity in the lot.

Orphenadrine Citrate ER Tablets are used as an adjunct to rest, physical therapy and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions. The product is packaged in 100-count and 1000-count bottles and was distributed nationwide in the USA to wholesalers and distributors.

Product Name	NDC Number	Lot Number	Expiration Date	Date of Manufacture
Orphenadrine Citrate ER Tablets	0185-0022-01	JX6411	05/2022	5/24/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	JX6413	05/2022	5/24/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	KC0723	08/2022	8/21/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	KC3303	08/2022	8/21/2019

Product Name	NDC Number	Lot Number	Expiration Date	Date of Manufacture
Orphenadrine Citrate ER Tablets	0185-0022-01	KE4348	11/2022	11/6/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	KE7169	11/2022	11/6/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	KE4349	11/2022	11/6/2019
Orphenadrine Citrate ER Tablets	0185-0022-01	KL3199	03/2023	3/3/2020
Orphenadrine Citrate ER Tablets	0185-0022-01	KM0072	03/2023	3/3/2020
Orphenadrine Citrate ER Tablets	0815-022-10	KS3939+	03/2023	3/3/2020
Orphenadrine Citrate ER Tablets	0185-0022-01	LA7704	10/2023	10/6/2020
Orphenadrine Citrate ER Tablets	0185-0022-01	LA7703	10/2023	10/6/2020
Orphenadrine Citrate ER Tablets	0185-0022-01	LA9243	11/2023	11/18/2020

+ 1,000-count bottle

This recall of Orphenadrine Citrate ER Tablets is specific to the lots listed above and does not apply to any other strengths of Sandoz Orphenadrine Citrate ER Tablets nor to other lot numbers of the product. Any product returned that is not associated with this recall will be destroyed, and no credit will be issued.

Sandoz is notifying its wholesalers and distributors by mail and is arranging for the return of all recalled product. Wholesalers and distributors that have Orphenadrine Citrate ER Tablets subject to this recall should immediately stop distribution of the recalled product and quarantine and return all recalled product in their inventory.

Consumers who have Orphenadrine Citrate ER Tablets being recalled should stop taking the recalled product and immediately consult with their physician to obtain another prescription. 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.

Retailers and consumers should contact Sedgwick directly by phone at 844-491-7869 or email at sandoz4887@sedgwick.com to return the recalled product. Representatives are available Monday – Friday, 8:00 am – 5:00 pm ET.

To report an adverse reaction, please contact Sandoz by phone at (800) 525-8747 or by email at qa.drugsafety@sandoz.com. Customer service agents are available Monday – Friday from 8:30 am to 5:00 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.

Company Contact Information

Consumers:

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Media:

Leslie Pott
201-354-0279

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