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

Date: 03/22/2022

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Sandoz has posted a lot recall of Orphenadrine Citrate 100 mg Extended-Release Tablets.

About this recall:
Sandoz Inc. ("Sandoz") is initiating a voluntary recall of 13 lots of oral Orphenadrine Citrate 100 mg Extended Release (ER) Tablets to the consumer level. The presence of a nitrosamine 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.

What this means to you:
Nitrosamines are 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 lots. 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.

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.

Consumers should contact Sedgwick by phone at 844-491-7869 Monday – Friday, 8:00 am – 5:00 pm EST or email at sandoz4887@sedgwick.com to return the recalled product. This recall of Orphenadrine Citrate ER Tablets is specific to the lots listed at the link on the following page and does not apply to any other strengths of Sandoz Orphenadrine Citrate ER Tablets nor to other lot numbers of the product.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-nationwide-recall-13-lots-orphenadrine-citrate-100-mg-extended-release-tablets-due

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.