

Sandoz - Recall of orphenadrine

- On March 21, 2022, <u>Sandoz announced</u> a voluntary consumer-level recall of some lots of <u>orphenadrine</u> extended-release (ER) tablets due to the presence of a nitrosamine impurity, Nitroso-Orphenadrine, which has the potential to be above the FDA's Acceptable Daily Intake limit of 26.5 ng/day.
- The recalled lots were distributed August 2019 to April 2021.

Product Description	NDC#	Lot# (Expiration Date)
Orphenadrine 100 mg ER tablets	0185-0022-01	JX6411 (05/2022); JX6413 (05/2022); KC0723 (08/2022); KC3303 (08/2022); KE4348 (11/2022); KE7169 (11/2022); KE4349 (11/2022); KL3199 (03/2023); KM0072 (03/2023); LA7704 (10/2023); LA7703 (10/2023); LA9243 (11/2023)
	0185-022-10	KS3939+ (03/2023)

- Orphenadrine 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.
- 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 recalled lots.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the recalled orphenadrine.
- Contact Sedgwick by phone at 1-844-491-7869 or by email at <u>sandoz4887@sedgwick.com</u> for more information about the recall.

Optum

At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.