Orphenadrine Citrate 100 mg Extended-Release Tablets Recall Alert

Date of Notice: March 22, 2022

Brief Description of Recall Alert

Sandoz Inc. is initiating a voluntary recall of thirteen (13) lots of oral orphenadrine citrate 100 mg extended release (ER) tablets. 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's acceptable daily intake limit 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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
orphenadrine citrate ER tablets, 100 mg	0185-0022-01	JX6411	05/2022
		JX6413	
		KC0723	08/2022
		KC3303	
		KE4348	11/2022
		KE7169	
		KE4349	
		KL3199	03/2023
		KM0072	
		LA7704	10/2023
		LA7703	
		LA9243	11/2023
orphenadrine citrate ER tablets, 100 mg	0185-0022-10	KS3939+	03/2023

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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Prescriber Information

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, quarantine, and return all recalled product in their inventory. To date, Sandoz has not received any reports of adverse events related to the presence of a nitrosamine impurity in the lot.

Retailers and prescribers 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 EST.

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 EST.

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

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the product being recalled, should contact Sedgwick directly by phone at 844-491-7869 or email at sandoz4887@sedgwick.com. Representatives are available Monday – Friday, 8:00 am – 5:00 pm ET.

RxAdvance Response

Members should continue taking orphenadrine citrate 100 mg ER tablets until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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