COMMUNICATION

COM-2022-019

04
APRIL
2022

# Recall Notification

## PharmPix Clinical Department


PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

## U.S. Food & Drug Administration Publication Date:

03/22/2022

## Drug Information:

National Drug Code

0185-0022-01

Product Description

Orphenadrine citrate 100mg extended-release (ER) tablets

Lot Number

Refer to table in this notification for product details.

Expiration Date

Refer to table in this notification for product details.

## Company:

Sandoz Inc.

QUESTIONS

Call Sedgwick at 844-491-7869 or email sandoz4887@sedgwick.com

Monday – Friday from 8:00 a.m. to 5:00 p.m. ET.

REPORT AN ADVERSE REACTION

Call Sandoz at 800-525-8747 or email qa.drugsafety@sandoz.com.

## Orphenadrine citrate ER tablets

It is for this reason that we are notifying you that on 03/22/2022 the US Food and Drug Administration published a drug recall for the following product(s): orphenadrine citrate ER tablets.

### Pharmacy Required Action:

**Identify** if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

**Advise** patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

### Reason for Recall:

Sandoz Inc. is voluntarily recalling 13 lots of orphenadrine citrate 100mg ER tablets to the consumer level. The presence of nitrosamine, potentially above the FDA acceptable daily intake limit of 26.5ng/day, was detected in the lots during recent testing.

Nitrosamines have the risk of causing cancer when present above the allowable exposure limits. To date, Sandoz Inc. has not received any reports of adverse events related to the presence of a nitrosamine impurity in the lot. The product was distributed nationwide in the USA to wholesalers and distributors.

Sandoz is notifying its wholesalers and distributors by mail and is arranging for the return of all recalled products. Retailers and consumers should contact Sedgwick to return the called product.

The NDC, lot number and expiration date details of the products that were recalled are indicated in the table below.

| Product Name | NDC Number | Lot Number | Expiration Date |
|---|---|---|---|
| Orphenadrine citrate 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 |
| | | KS3939 | 03/2023 |
| | | LA7704 | 10/2023 |
| | | LA7703 | 10/2023 |
| | | LA9243 | 11/2023 |

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.



pharmpix
POWERED BY ONEARK

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:
1. U.S. Food and Drug Administration. (2022). Sandoz, Inc. Issues Nationwide Recall of 13 Lots of Orphenadrine Citrate 100mg Extended Release Tablets Due to Presence of a Nitrosamine Impurity. 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
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
FRM-CL-000126-000

CLINICAL PEARLS BY PHARMPIX