## Sandoz – Recall of orphenadrine

- On March 21, 2022, Sandoz announced a voluntary consumer-level recall of some lots of orphenadrine 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);<br>JX6413 (05/2022);<br>KC0723 (08/2022);<br>KC3303 (08/2022);<br>KE4348 (11/2022);<br>KE7169 (11/2022);<br>KE4349 (11/2022);<br>KL3199 (03/2023);<br>KM0072 (03/2023);<br>LA7704 (10/2023);<br>LA7703 (10/2023);<br>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 **sandoz4887@sedgwick.com** for more information about the recall.