Mass General Brigham
Health Plan

Drug Recall

DATE OF RECALL: March 23, 2022

DRUG NAME: Orphenadrine Citrate ER 100mg Tablets

RECALLING FIRM: Sandoz, Inc

REASON FOR RECALL: This recall was issued due to the presence of a nitrosamine (N-methyl-N-nitroso-2-[(2-methylphenyl) phenyl methoxy ethanamine (NMOA or Nitroso-Orphenadrine)) 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.

FDA LINK: 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

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Orphenadrine Citrate ER Tablets, 100 Count	00185-0022-01	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
Orphenadrine Citrate ER Tablets, 1000 Count	00185-0022-10	KS3939	03/2023