



Drug Recall

DATE OF RECALL: December 7, 2021

DRUG NAME: Lidocaine Hydrochloride Topical Solution 4% (40 mg/ mL) 5ml

RECALLING FIRM: Teligent Pharma, Inc.

REASON FOR RECALL: This recall was issued because the firms testing has found it to be super potent based on an Out of Specification (OOS) result obtained at the 9-month (Lot 16345) and 18-month (Lot 15594) stability timepoint.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teligent-pharma-incs-issues-worldwide-voluntary-recall-lidocaine-hcl-topical-solution-usp-4-due>

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Lidocaine Hydrochloride Topical Solution 4% (40 mg/ mL), 50 mL bottle	63739-0997-64	16345	01/2024
Lidocaine Hydrochloride Topical Solution 4% (40 mg/ mL), 50 mL bottle	63739-0997-64	15594	05/2023