Teligent Pharma, Inc.'s Issues Worldwide Voluntary Recall of Lidocaine HCl Topical Solution 4%

Due to Super Potency

Company Contact:
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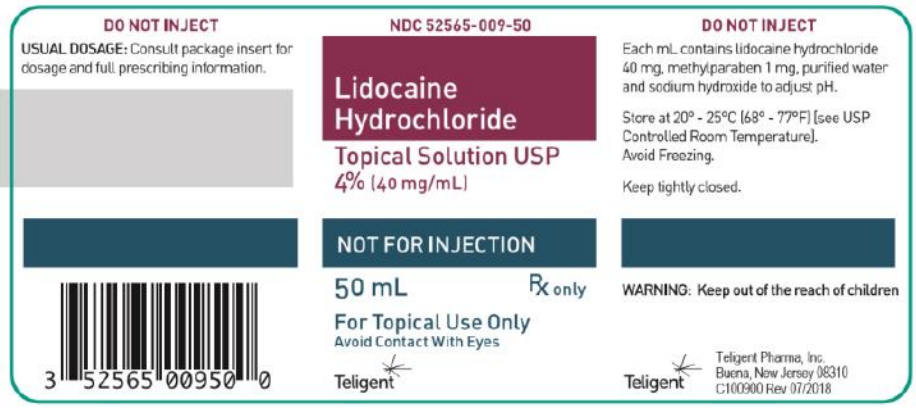
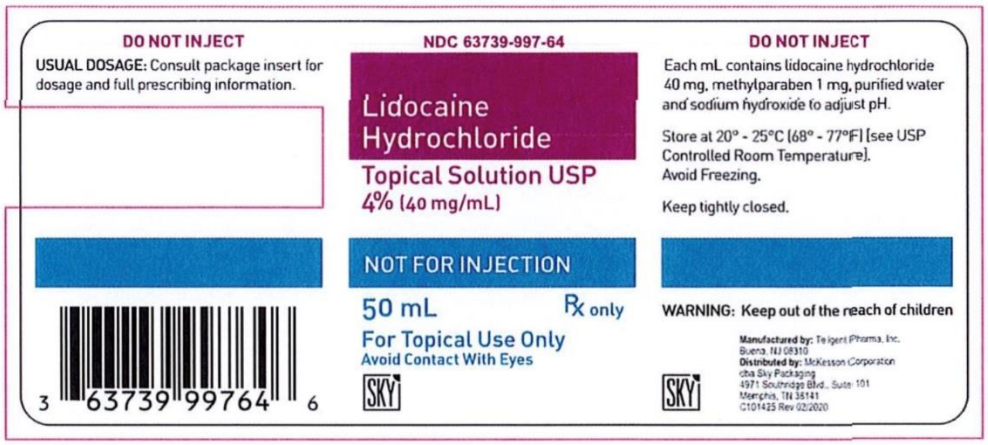
FOR IMMEDIATE RELEASE –12 October 2021 – Buena, NJ, Teligent Pharma, Inc. is voluntarily recalling the five lots of Lidocaine HCl Topical Solution 4%, 50ml in a screw cap glass bottle listed in the table below to the user level. The product is being recalled because the firms testing has found it to be super potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint.

Risk Statement: Use of the super potent product would result in a higher than intended lidocaine dose above that intended. An increased lidocaine dose could lead to the development of local anesthetic systemic toxicity depending on the duration of the treatment and the specific patient. Local anesthetic systemic toxicity can result in central nervous system reactions including excitation and/or depression and more serious signs of cardiovascular toxicity, such as bradycardia, hypotension, and even cardiovascular collapse can present very quickly. If local anesthetic systemic toxicity is not recognized and treated quickly, severe morbidity and even death can result. Adults and the elderly who are more likely to use this product as well as children of lower body weight are more likely to experience local anesthetic systemic toxicity if a higher than intended lidocaine concentration is administered. To date, Teligent Pharma, Inc. has not received any reports of adverse events related to this recall.

Product	NDC	Lot Number	Expiration
Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL bottle	52565-009-50	13262	03/2022
		14217	08/2022
		13058	02/2022
		13768	05/2022
	63739-997-64	16306	01/2024

The product is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract and is packaged in a 50ml glass bottle with a screw cap with the identification NDC# 52565-009-50 and 63739-997-64. The product can be identified by the following labeling: Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL). Product was distributed at the wholesale and retail distribution levels in the US and Canada.





Teligent Pharma, Inc. is notifying its distributors via Fed-Ex and is arranging for return of all recalled products.

Consumers and patients that have Lidocaine HCl Topical Solution 4% which is being recalled are asked to discontinue use and dispose of the product immediately.

Consumers can call 1-856.697.1441 press * to reach the medical information call center Monday through Friday, 8am – 5pm or send an e-mail to **Medical@teligent.com** for any product or recall related questions for Lot #13262 Exp. 03/2022, Lot #14217 Exp. 08/2022, Lot #13058 Exp. 02/2022, Lot #13768 Exp. 05/2022, Lot #16306 Exp. 01/2024.

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

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**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.