



Teligent Pharma – Recall of lidocaine topical solution

- On December 7, 2021, [Teligent Pharma announced](#) a voluntary, patient-level recall of two lots of [lidocaine topical solution 4%](#) because testing has found it to be super potent based on an out of specification result obtained at the 9-month and 18-month stability timepoints.
 - Other lidocaine topical solutions that are not being recalled are available for patients to use.
- The product was distributed nationwide in the U.S.

Product Description	NDC#	Lot# (Expiration Date)
Lidocaine topical solution 4% (40 mg/mL), 50 mL bottle	63739-997-64	15594 (05/2023); 16345 (01/2024)

- Lidocaine topical solution 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.
- Per Teligent, use of the super potent product would result in a higher than intended lidocaine dose, which 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 has not received reports of any adverse events attributed to the recalled lots.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled lidocaine topical solution.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Teligent Pharma by phone at **1-856-697-1441** or by email at Medical@teligent.com for more information about this recall.



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