

Teligent Pharma – Recall of lidocaine topical solution

 On August 27, 2021, <u>Teligent Pharma announced</u> a voluntary, patient-level recall of one lot of <u>lidocaine topical solution 4%</u> because testing has found it to be super potent based on an out of specification result obtained at the 18-month stability timepoint.

| Product Description | NDC# | Lot# (Expiration Date) |
|--------------------------------------------------------|--------------|---------------------------|
| Lidocaine topical solution 4% (40 mg/mL), 50 mL bottle | 52565-009-50 | 14218 (09/2022) |

- 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.
- 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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