

URGENT RECALL: Lidocaine HCl Topical Solution 4% (Lot# 14218; Exp: 09/2022)

9/3/2021

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Dial **1-856-697-1441** and **Press ***

This is to inform you of a product recall involving **Lidocaine HCl Topical Solution 4% in a 50ml screw cap glass bottle with Lot Number: 14218; Expiry Date: 09/2022 and NDC# 52565-009-50**

The product can be identified by the following label on the container:



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**.

This recall has been initiated because the firm's testing has found the Product to be super potent. Use of the super potent product would result in a higher than intended lidocaine effect.

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

Teligent Pharma, Inc. is notifying its customers via this letter and is seeking discontinuation and disposal of all recalled products with the following details:

Product	NDC Code	Lot Number	Expiry Date
Lidocaine Hydrochloride Topical Solution, USP 4%, 50ml	52565-009-50	14218	September 2022

Consumers that have the product being recalled are asked to discontinue use immediately and dispose of the material.

Disposing medicines in household trash please follow these steps:

1. Remove the drugs from their original containers and mix them with something undesirable, such as used coffee grounds, dirt, or cat litter. This makes the medicine less appealing to children and pets and unrecognizable to someone who might intentionally go through the trash looking for drugs.
2. Put the mixture in something you can close (a re-sealable zipper storage bag, empty can, or other container) to prevent the drug from leaking or spilling out.
3. Throw the container in the garbage.
4. Scratch out all your personal information on the empty medicine packaging to protect your identity and privacy. Throw the packaging away.

For any product questions or further information about this recall please contact Teligent Pharma Inc at **1-856-697-1441** and **press *** or email us to Medical@teligent.com.

You can also contact your physician, healthcare provider or 911 if you experience 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 made with the knowledge of the U.S Food and Drug Administration.

For more information, please refer to the Press Release by clicking on URL: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls>