Teligent Pharma – Recall of lidocaine topical solution

- On October 12, 2021, Teligent Pharma announced a voluntary, patient-level recall of five 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 18-month stability timepoint.
    - Clinical Services through the Drug Safety Notification program will conduct a mailing to members and send electronic messaging to providers that may be affected by this recall.
    - The letter instructs members on how to identify the recalled product. If they have the recalled product on hand, they are advised to not use it and to contact their pharmacy for a replacement.
    - A healthcare provider should be contacted for any questions regarding their therapy.
    - Lidocaine topical solution that is not being recalled is available for patients to use.

Product Description	NDC#	Lot# (Expiration Date)
Lidocaine topical solution 4% (40 mg/mL), 50 mL bottle	52565-009-50	13262 (03/2022); 14217 (08/2022); 13058 (02/2022); 13768 (03/2022)
	63739-997-64	16306 (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.