



Teligent, Inc.  
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**2<sup>ND</sup> RECALL NOTICE  
CUSTOMER RECALL NOTIFICATION**

**URGENT: Teligent Lidocaine Hydrochloride Topical Solution, USP 4%, 50ml Recall**

Date: 27Aug2021

Dear Valued Customer:

Recently, you were notified that Teligent is voluntarily recalling the following product. This notification is to inform you that this recall is now being carried out to the **Consumer level**.

Product	NDC Code	Lot Number	Expiry Date	Distribution Dates
Lidocaine Hydrochloride Topical Solution, USP 4%, 50ml	52565-009-50	14218	September 2022	12/12/19 – 1/27/20

The product is being recalled because the firm's testing has found it to be super potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint. This recall is being made with the knowledge of the Food and Drug Administration and should be carried out to the **consumer level**.

**\*Consumers and patients should return their unused product to the pharmacy where it was purchased.**

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Wholesalers/Distributors and Pharmacies, immediately discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.
3. Wholesalers/Distributors and Pharmacies **only** return product to:

**Eversana**  
**c/o Teligent Recall**  
ATTN: Returns Department  
4580 S. Mendenhall  
Memphis, TN 38141

**NOTE: Wholesalers/Distributors/Pharmacies.** To request a prepaid shipping label please complete and return the enclosed "Customer Recall Return Response Form" to the email or fax below (section 5). Wholesalers, please include debit memo. The prepaid shipping label will be sent to the email address provided. The email will be coming from EVERSAANA within 5 business days. Please check the spam folder if you do not see it in your inbox. **Please note the FedEx link is only valid for 10 days.**

Pharmacies: credit will be issued to your wholesaler on your behalf.

4. If you have further distributed this product, please identify, and notify your customers at once of this product recall. Your notification should include a copy of this recall notification letter and customer response form.
5. Wholesalers/Distributors and Pharmacies, please complete and return the enclosed "Customer Recall Return Response Form," even if you do not have any inventory, as soon as possible and email the form to us at [DDNRegulatory@Eversana.com](mailto:DDNRegulatory@Eversana.com) and CC: [TeligentCS@Eversana.com](mailto:TeligentCS@Eversana.com). The completed form may also be faxed to 1-414-434-6695.

We apologize for any inconvenience this may cause you. Wholesalers/Distributors and Pharmacies, if you have any questions, please do not hesitate to call our Customer Service at 877-622-2330, option 1; M-F 8 am – 7 pm CDT. **Consumers and patients should contact their physician or pharmacy for further medical advice.**

Thank you,  
Teligent Customer Service Team



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### Customer Recall Return Response Form

Product	NDC Code	Lot Number	Quantity to be returned	Expiry Date	Distribution Dates
Lidocaine Hydrochloride Topical Solution, USP 4%, 50ml	52565-009-50	14218		September 2022	12/12/19 – 1/27/20

\*Note: Total number of unopened bottles only.

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the recall letter.
- I have checked my inventory and do not have the recalled product.
- I have checked my inventory and have quarantined the product consisting of \_\_\_\_\_ unit(s).
- I would like to receive a pre-paid return label. Total number of Call Tags (Number of Boxes you will be returning): \_\_\_\_\_

Return product to: **Eversana Life Science Services**  
 c/o Teligent Recall  
 ATTN: Returns Department  
 4580 S. Mendenhall Rd.  
 Memphis, TN 38141

**Note:** A prepaid shipping label will be sent to the email address provided below. The email will be coming from EVERSANA within 5 business days. Please check the spam folder if you do not see it in your inbox. Please note the FedEx link is only valid for 10 days.

Consumers and patients should return their unused product to the pharmacy where it was purchased.

- I have or will contact those further distributed to. This recall is to the consumer level.

Any adverse events associated with this recalled product?  Yes  No  
 If yes, please explain: \_\_\_\_\_

Check the appropriate box(es) to describe your business:  
 Wholesaler/distributor     Hospital/medical facility     Pharmacy-retail     Other: \_\_\_\_\_

\* Required fields must be completed to initiate call tag request.

Contact Information:

\*Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title: \_\_\_\_\_ \*Tel Number: \_\_\_\_\_

\*Email: \_\_\_\_\_

\*Facility Name: \_\_\_\_\_

\*Facility Address: \_\_\_\_\_

\*City \_\_\_\_\_ \*State \_\_\_\_\_ \*Zip \_\_\_\_\_

\*Debit Memo \_\_\_\_\_ (Wholesalers: please include debit memo along with completed response form)

\*\*Pharmacy required fields

\*\*Wholesaler: \_\_\_\_\_ \*\*WholesalerAccount#: \_\_\_\_\_

\*\* Pharmacy DEA # \_\_\_\_\_

**Wholesalers/Distributors and Pharmacies, even if you do not have inventory, please send completed recall response form to: Email [DDNRegulatory@Eversana.com](mailto:DDNRegulatory@Eversana.com) and [TeligentCS@Eversana.com](mailto:TeligentCS@Eversana.com) or Fax 1-414-434-6695**