



<<Date>>

<<First Name>> <<Last Name>>

<< Address line 1>>

<< Address line 2>>

<<City>> <<ST>> << Zip Code>>

IMPORTANT RECALL INFORMATION

Dear <<First Name>> <<Last Name>>,

We are sending you information about [drug name] that may be valuable to you.

On August 27, 2021, Teligent issued a recall of Lidocaine Topical Solution 4% 50 mL. **This recall was issued because testing found a sample from one lot of the product to be super potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint.** This means the product could be stronger than it should be.

This may represent a potential health hazard or safety risk to patients using product affected by this recall.

Our records show you may have received a prescription for this medicine recently from your retail pharmacy.

According to Teligent, using super potent product would cause a higher than intended lidocaine dose, which could lead to the development of local anesthetic systemic toxicity depending on how long the product was used and the specific patient. Local anesthetic systemic toxicity can cause central nervous system (brain and spinal cord) reactions including excitation and/or depression and more serious signs of cardiovascular toxicity, such as bradycardia (low pulse rate), hypotension (low blood pressure), and even cardiovascular collapse can present very quickly. If local anesthetic systemic toxicity is not noticed 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.

According to Teligent Pharma, Inc., as of the date of recall, it has not received any reports of adverse events related to this recall.

This recall affects lot number 14218 exp. September 2022.

To see if you have affected product, please check the lot number. The lot number can be found on the bottom of the manufacturer's container and on the manufacturer's label on the carton. If the product you have is not from one of these affected lot numbers, it is not affected by this recall. If your product is from one of these affected lot numbers, please contact the pharmacy that filled your prescription for further instructions.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information. This information is not a substitute for medical advice or treatment. Talk to your doctor or health care provider about this information and any health-related questions you have. CVS Caremark assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result of this information.

Teligent recommends that consumers and patients should return unused product to the pharmacy where it was purchased. Consumers and patients should contact their physician for further medical advice.

Please call your doctor right away for advice if you may be using affected product or if you do not know if you used affected product or not. Your doctor is familiar with your medical history and can suggest the best treatment for you. If you need a prescription for a different medicine, please contact your doctor.

For more information, please call Teligent toll-free at 1-877-622-2330, Monday through Friday, 8:00 am to 7:00 pm (CT). You may also call the U.S. Food and Drug Administration toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

- This material is available in other languages. Please call our member services department at the toll-free number listed on your benefit ID card. TTY users should call 1-800-863-5488.
- Esta información está disponible en otros idiomas. Por favor llame a nuestro departamento de servicios al cliente al número gratuito que aparece en su tarjeta de identificación. Los usuarios de equipo teleescritor (TTY) deben llamar al 1-800-863-5488.

Sincerely,

CVS Caremark® Medical Affairs