



<<Date>>

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

<< Address line 1>>

<< Address line 2>>

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

### **RECALL NOTICE**

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

Our records indicate that you may have recently received a prescription for Lansoprazole Delayed Release Orally Disintegrating (ODT) Tablets manufactured by Dr. Reddy's Laboratories from your retail pharmacy. We are writing to inform you of limited recalls that have been issued for certain lot numbers of these products.

On July 23, 2022, the United States Food and Drug Administration (FDA) published its classification of the recalls of certain lots of Lansoprazole Delayed Release Orally Disintegrating (ODT) Tablets manufactured by Dr. Reddy's Laboratories, Class II recalls. According to the manufacturer, these products are being recalled due to out-of-specification results observed in dissolution test in one lot (T2100514) of the 15mg product during long term stability testing, and the second lot (T2100515, 30mg product) is also being recalled as a precautionary measure as it was manufactured from the same common blend as of the OOS lot (T2100514, 15mg product).

According to the manufacturer, due to higher dissolution results, the therapeutic concentration of the drug may fluctuate marginally during the day, but it may not alter the therapeutic benefit and is unlikely to cause any serious adverse effects to the patients consuming the subject lot (T2100514) and the other impacted lot (T2100515).

**The manufacturer issued this recall on July 13, 2022 to wholesalers and pharmacies only. The manufacturer is not requiring any action on the part of consumers in this recall.**

**Product:** Lansoprazole Delayed-Release Orally Disintegrating 15mg Tablets, 10X10 Blister

**NDC:** 43598-0560-78

**Lot Number/Expiration Date:** T2100514 exp. 01/2023

**Product:** Lansoprazole Delayed-Release Orally Disintegrating 30mg Tablets, 10X10 Blister

**NDC:** 43598-0561-78

**Lot Number/Expiration Date:** T2100515 exp. 01/2023

Please contact your prescriber with any questions or concerns about this recall or your use of the product(s).

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.

For more information, please call Dr. Reddy's Laboratories toll-free at 1-888-375-3784 or by email at [medinfo@drreddys.com](mailto:medinfo@drreddys.com). 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](http://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,

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