



<<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 Ketorolac Tromethamine 30 mg/1 mL Injection manufactured by Fresenius Kabi that may be valuable to you.

On February 3, 2021, the United States Food and Drug Administration (FDA) published a notice regarding a Class I recall of Ketorolac Tromethamine 30 mg/1 mL Injection manufactured by Fresenius Kabi. **This recall was issued because particulate matter was found in reserve samples. The presence of particulate matter in this product could be a 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.

A complete list of the affected products and lot numbers is provided at the end of this letter.

To see if you have affected product, please check the lot number. The lot number is on the right hand side of the manufacturer's label by the bar code on the vial. If your product is not from one of these affected lots, 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.

Fresenius has advised that patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Please call your healthcare provider right away for advice if you may be using affected product or if you do not know if you used affected product. Your doctor is familiar with your medical history and can suggest the best treatment option for you. If you need a prescription for a different medicine, please contact your doctor.

For more information, call Fresenius Kabi toll-free at 1-866-716-2459 Monday through Friday, 8:00 AM to 5:00 PM (CST). You may also call the FDA toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

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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.

- 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

Affected Products and Lot Numbers:

Affected Product	NDC #	Lot #
Ketorolac Tromethamine 30 mg/1 mL Injection, 1 mL Single-Dose Vial	63323-0162-01	6121083 exp. 02/2021
Ketorolac Tromethamine 30 mg/1 mL Injection, 1 mL Single-Dose Vial, 25 Vials per Tray	63323-0162-00	6121083 exp. 02/2021