COMPANY ANNOUNCEMENT

Fresenius Kabi Issues Voluntary Nationwide Recall of Ketorolac Tromethamine Injection, USP Due to the Presence of Particulate Matter

Summary

Company Announcement Date:

January 08, 2021

FDA Publish Date:

January 08, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of particulate matter

Company Name:

Fresenius Kabi USA

Brand Name:

Fresenius Kabi

Product Description:

Ketorolac Tromethamine Injection, USP, 30 mg/mL

Company Announcement

Fresenius Kabi USA is voluntarily recalling a single lot of Ketorolac Tromethamine Injection, USP, 30 mg/mL, 1 mL fill in a 2 mL amber vial to the user level due to the presence of particulate matter. Particulate matter was found in reserve sample vials. No adverse event reports have been received for the recalled lot, which was produced and sold in 2019.

Administration of products containing particulate matter could obstruct blood vessels and result in local irritation of blood vessels, swelling at the site of injection, a mass of tissue that could become inflamed and infected, blood clots traveling to the lung, scarring of the lung tissues, and allergic reactions that could lead to life-threatening consequences.

Ketorolac Tromethamine, a nonsteroidal anti-inflammatory drug, is indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level. The total combined duration of use of oral Ketorolac Tromethamine and Ketorolac Tromethamine Injection should not exceed 5 days.

Listed below is a table of the recalled lot distributed nationwide in the United States to wholesalers, distributors, hospitals, and pharmacies between March 28, 2019 and September 3, 2019. An image of the label is also included below.

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial	63323-162-01	160201	6121083	02/2021	03/28/2019	09/03/2019

Fresenius Kabi is notifying its distributors and customers by letter and asking customers and distributors to check their stock immediately and to quarantine and discontinue the use and distribution of any affected product. Distributors should notify their customers and direct them to quarantine and discontinue distributing or dispensing the affected lot, and to return the product to Fresenius Kabi. The recall letter and response form are available at https://www.fresenius-kabi.com/us/pharmaceutical-product-updates. (https://www.fresenius-kabi.com/us/pharmaceutical-product-updates) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Customers with questions regarding this recall may contact Fresenius Kabi at 1-866-716-2459 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Time. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
- Or, contact Fresenius Kabi at 1-800-551-7176, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. or via email at: productcomplaint.USA@fresenius-kabi.com (mailto:productcomplaint.USA@fresenius-kabi.com) or adverse.events.USA@fresenius-kabi.com (mailto:adverse.events.USA@fresenius-kabi.com)

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Fresenius Kabi

Fresenius Kabi (www.fresenius-kabi.com/us (http://www.fresenius-kabi.com\us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. The company's U.S. headquarters is in Lake Zurich, Illinois. The company's global headquarters is in Bad Homburg, Germany. For more information about Fresenius Kabi worldwide, please visit www.fresenius-kabi.com (http://www.fresenius-kabi.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

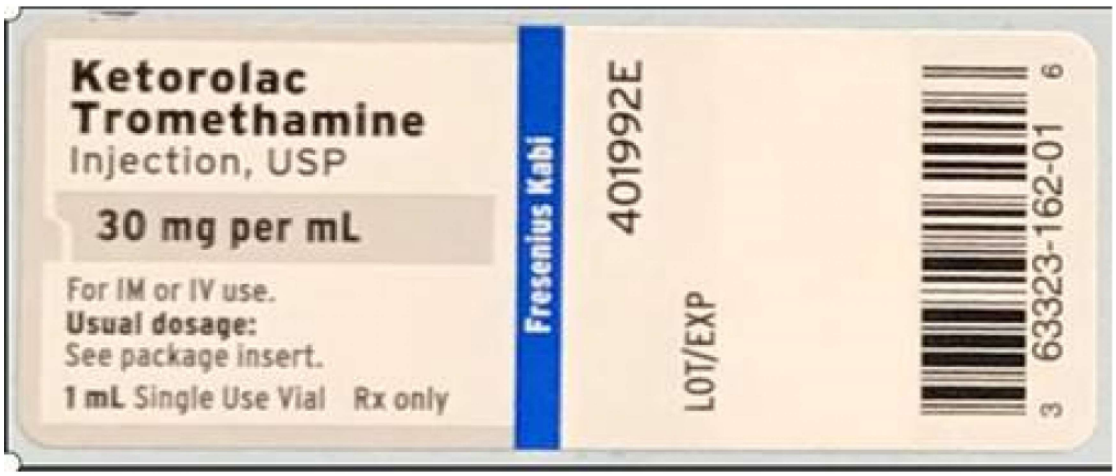
Company Contact Information

Consumers:

Fresenius Kabi

1-866-716-2459

Product Photos



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