January 12, 2021 COM-2021-005

RECALL NOTIFICATION

FDA PUBLICATION DATE:

January 8, 2021

DRUG NAME: Ketorolac Tromethamine Injection, USP, 30 mg/mL

COMPANY: Fresenius Kabi USA

REASON: Presence of particulate matter

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. For this reason, we are notifying you that on January 8, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary recall for a single lot of Ketorolac Tromethamine Injection, USP, 30 mg/mL, manufactured by Fresenius Kabi USA.

Affected products:

NDC	Product description	Batch Number	Expiration Date
63323-0162-01	Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial	6121083	02/2021

The voluntary recall is due to the presence of particulate matter found in sample vials from the lot, which was produced and sold in 2019. No adverse event reports have been received.

Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returning to the place of purchase or as directed in the recall notification.
- Advise patients to contact their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their healthcare provider if they have experienced any problems related to using this drug product.

Contact information: For further details, 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.

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Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download the FDA Form 3500 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.

Additional information can be found at:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Fresenius Kabi Issues Voluntary Nationwide Recall of Ketorolac Tromethamine Injection, USP Due to the Presence of Particulate Matter. January 8, 2021, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-ketorolac-tromethamine-injection-usp-due-presence

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