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April 21, 2020 **COM-2020-033**

RECALL NOTIFICATION

DATE:
April 20, 2020

DRUG NAME:
Ketorolac Tromethamine Injection, USP, 30 mg/mL, and Ketorolac Tromethamine Injection, USP, 60 mg/2 mL

COMPANY:
Fresenius Kabi USA, LLC

REASON:
Presence of Particulate Matter

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected product:

Product Name	Product Code	NDC	Batch & Expiration Day
Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial	160201	63323-0162-01	6118737, 04/2020
			6118902, 04/2020
			6119052, 05/2020
			6119752, 08/2020
			6122349, 07/2021
			6122538, 09/2021
Ketorolac Tromethamine Injection, USP, 60 mg / 2 mL (30 mg / mL), 2 mL fill in a 2 mL amber vial	160202	63323-0162-02	6119229, 06/2020
			6119273, 06/2020
			6119843, 09/2020
			6121115, 02/2021
			6121451, 03/2021
			6121452, 03/2021
			6121496, 03/2021

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug, and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Contact information:

- Customers: 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.

Note:
Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch

Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm

- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

- 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 or adverse.events.USA@fresenius-kabi.com

Additional information:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-13-lots-ketorolac-tromethamine-injection-usp-due
  https://www.fresenius-kabi.com/us/pharmaceutical-product-updates

Best regards,

PharmPix Clinical Department

Reference:

- Center for Drug Evaluation and Research. (2020, April 20). Fresenius Kabi Issues Voluntary Nationwide Recall of 13 Lots of Ketorolac Tromethamine Injection, USP Due to the Presence of Particulate Matter in Reserve Samples. Retrieved April 21, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-13-lots-ketorolac-tromethamine-injection-usp-due