

Ketorolac tromethamine injection Recall Alert

Date of Notice: 04/20/2020

Brief Description of Recall

On April 20, 2020, Fresenius Kabi USA, LLC is voluntarily recalling 13 lots of ketorolac tromethamine injection due to the presence of particulate matter composed of carbon, silicon, oxygen and polyamides.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Ketorolac injection, USP, 30mg/ml, 1ml fill in a 2ml vial	63323-162-01	6118737	04/2020
		6118902	
		6119052	
		6119752	
		6122349	
		6122538	
Ketorolac injection, USP, 60mg/ml, 2ml fill in a 2ml vial	63323-162-02	6119229	06/2020
		6119273	00/2020
		6119843	09/2020
		6121115	02/2021
		6121451	
		6121452	03/2021
		6121496	

Prescriber Information

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
- Regular Mail or Fax: <u>Download form</u> 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

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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Member Information

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.

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.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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