RXADVANCE
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Southborough, MA 01772

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 6118902 6119052 6119752 6122349 6122538	04/2020
Ketorolac injection, USP, 60mg/ml, 2ml fill in a 2ml vial	63323-162-02	6119229 6119273	06/2020
		6119843	09/2020
		6121115	02/2021
		6121451 6121452 6121496	03/2021

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: Download form 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

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.