RXADVANCE
136 Turnpike Rd
Southborough, MA 01772

ketorolac tromethamine injection Recall Alert

Date of Notice: 01/08/2021

Brief Description of Recall Alert

On January 8, 2021, Fresenius Kabi USA, LLC is voluntarily recalling a single lot of ketorolac tromethamine 30 mg/mL injection, USP, due to the presence of particulate matter. Particulate matter was found in reserve sample vials.

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 tromethamine 30 mg/mL injection, USP	63323-162-01	6121083	02/2021

Prescriber 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. The recall letter and response form are available at https://www.fresenius-kabi.com/us/pharmaceutical-product-updates. No adverse event reports have been received for the recalled lot, which was produced and sold in 2019.

Adverse reactions or quality problems experienced with the use of this drug 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

Members 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. Members should contact their doctor or health care provider if they have experienced any problems that may be related to taking or using this drug product.

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RxAdvance Response

RxAdvance recommends that you speak to your doctor before you stop taking the drug. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.