Fresenius Kabi – Recall of ketorolac injection

- On December 23, 2020, Fresenius Kabi announced a voluntary, user level recall of one lot of ketorolac injection, due to particulate matter.
    - This is an expansion to the recall of one lot of ketorolac injection that was announced on December 17, 2020.
    - Fresenius Kabi is only recalling some vials of ketorolac injection. Other ketorolac injection vials are available for patients to use and are not being recalled.
- The recalled lot is listed below.

Product Description	NDC#	Lot# (Expiration Date)
Ketorolac injection 30 mg/mL, 1 mL fill in a 2 mL amber vial	63323-162-01	6121083 (02/2021)

- Ketorolac tromethamine is indicated for the short-term (≤ 5 days) management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting.
- Administration of ketorolac injection 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 travelling to the lung, scarring of the lung tissues, and allergic reactions that could lead to life-threatening consequences.
- To date, no adverse events have been reported to Fresenius Kabi related to this recall.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled ketorolac injection.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Fresenius Kabi Medical Affairs at **1-800-551-7176** for further information about the recall or the Fresenius Kabi Quality Assurance Department at **1-866-716-2459** for information on how to return product.

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