Fresenius Kabi – Recall of ketorolac injection

- On April 20, 2020, Fresenius Kabi announced a voluntary, user level recall of 13 lots of ketorolac injection due to the presence of particulate matter composed of the following elements: carbon, silicon, oxygen and polyamides. Particulate matter was found in eight reserve sample vials.

- Listed below is a table of the recalled lots. These products were distributed between May 5, 2018 and December 16, 2019:

Product Description	NDC#	Lot# (Expiration Date)
Ketorolac tromethamine injection, 30 mg/mL, 1 mL fill in a 2 mL amber vial	63323-162-01	6118737 (4/2020); 6118902 (4/2020); 6119052 (5/2020); 6119752 (8/2020); 6122349 (7/2021); 6122538 (9/2021)
Ketorolac tromethamine injection, 60 mg/2 mL (30 mg/mL), 2 mL fill in a 2 mL amber vial	63323-162-02	6119229 (6/2020); 6119273 (6/2020); 6119843 (9/2020); 6121115 (2/2021); 6121451 (3/2021); 6121452 (3/2021); 6121496 (3/2021)

- Ketorolac tromethamine, a nonsteroidal anti-inflammatory drug, is indicated for the short term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level.

- 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.

- Patients should contact their 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 distribution and quarantine the product immediately.

- Contact Fresenius Kabi by phone at **1-866-716-2459** for further information regarding this recall.