Extract:

Fresenius Kabi USA is voluntarily recalling a single lot of Ketorolac Tromethamine Injection, USP, 30 mg/mL, 1 mL fill in a 2 mL amber vial to the user level due to the presence of particulate matter. Particulate matter was found in reserve sample vials. No adverse event reports have been received for the recalled lot, which was produced and sold in 2019.

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.

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. The total combined duration of use of oral Ketorolac Tromethamine and Ketorolac Tromethamine Injection should not exceed 5 days.

Full Text