carecentrix

Provider Newsflash April 20, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a voluntary recall issued by Fresenius Kabi USA, LLC of 13 lots of their Ketorolac Tromethamine Injection, USP, 30 mg/mL, 1 mL fill in a 2 mL amber vial and Ketorolac Tromethamine Injection, USP, 60 mg/2 mL (30 mg/mL), 2 mL fill in a 2 mL amber vial to the user level 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.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-13-lots-ketorolac-tromethamine-injection-usp-due?utm_campaign=Ketorolac%20Tromethamine%20Injection&utm_medium=email&utm_source=Eloqua
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by:
    - Faxing information– To: 919-792-6718 Attn: Quality Department

Thank you for your prompt attention and cooperation in this matter.