

Provider Newsflash January 11, 2021

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued a notice of a voluntary nationwide recall by Fesenius Kabi of one lot of their Ketorolac Tromethamine Injection, USP, 30 mg/ml, 1 ml fill in a 2 ml amber vial due to the presence of particulate matter which was found in reserve sample vials.

| Product Name/Product size | NDC | Product | Batch | Expiration | First Ship | Last Ship |
|--|------------------|---------|---------|------------|------------|------------|
| | Number | Code | Number | Date | Date | Date |
| Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial | 63323-162- 01 | 160201 | 6121083 | 02/2021 | 03/28/2019 | 09/03/2019 |

What do I need to do?

- Please review the following recall notice:
- <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-ketorolac-tromethamine-injection-usp-due-presence?utm_medium=email&utm_source=govdelivery</u>
- 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