

FDA Recall – Fresenius Kabi Famotidine Injection, USP 20 mg per 2 mL (10 mg per mL)

Purpose of this communication:

- We are writing to inform you that Fresenius Kabi USA, LLC has issued a voluntary recall of three lots (numbers 6133156, 6133194, 6133388) of Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL Fill in a 2 mL vial. The product is being recalled due to out-of-specification (OOS) endotoxin results of certain reserve samples from a single lot. Based upon the investigation, two additional lots were also included in the recall as a precautionary measure.
- Elevated endotoxin levels can precipitate severe systemic reactions such as sepsis and septic shock. Severe responses may include inflammatory and life-threatening immune responses and death. Non-serious adverse event reports potentially associated with the OOS have been received for one lot. These non-serious adverse events included chills, change in mental status, change in respiratory status, fever, increase in body temperature, shivering and shaking. To date, no adverse event reports have been received for the second and third lots.

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-three-lots-famotidine-injection-usp-20-mg-2-ml-10?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the 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 in advance for your cooperation and continued partnership.