

Company Announcement/Recall – Fresenius Kabi Sodium Acetate

Purpose of this communication:

We are writing to inform you that the FDA has issued notice of a voluntary recall by Fresenius Kabi, USA of seven lots of their Sodium Acetate Injection, USP 400 mEq/100 ml (4 mEq/ml), 100 ml fill in a 100 ml vial to the user level due to the presence of particulate matter found in reserve and/or stability sample vials.

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Sodium Acetate Injection, USP, 400 mEq/100 mL (4 mEq/mL), 100 mL fill in a 100 mL vial	63323-032-00	322100	6124193	05/2022	09/08/2020	12/22/2020
			6124196	05/2022	11/16/2020	01/27/2021
			6124226	05/2022	12/22/2020	03/22/2021
			6124532	06/2022	01/27/2021	04/13/2021
			6125333	12/2022	04/06/2021	06/01/2021
			6125678	01/2023	06/23/2021	09/27/2021
			6126846	08/2023	10/07/2021	11/17/2021

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-recall-sodium-acetate-injection-usp-due-presence-particulate-matter?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the 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.