

Hospira – Recall of sodium bicarbonate and atropine injection products

- On December 26, 2023, the <u>FDA announced</u> consumer level recalls of Hospira's <u>sodium</u> <u>bicarbonate 4.2%</u> injection, <u>sodium bicarbonate 8.4%</u> injection and <u>atropine</u> injection products because of the potential for the presence of glass particulate matter identified during product inspection.
- These products were distributed March 14, 2023 through June 29, 2023.

Product Description	NDC Number	Lot Number (Exp. date)
4.2% Sodium bicarbonate injection, ABBOJECT [®] glass syringe	Carton: 0409-5534-24 Case: 0409-5534-14	GX1542 (1/1/2025)
8.4% Sodium bicarbonate injection, Lifeshield [®] ABBOJECT [®] glass syringe	Carton: 0409-6637-24 Case: 0409-6637-14	HA7295 (3/1/2025)
Atropine sulfate injection, Lifeshield [®] ABBOJECT [®] glass syringe	Carton: 0409-4911-11 Case: 0409-4911-34	GY2496 (2/1/2025)

- Sodium bicarbonate injection is indicated in the treatment of metabolic acidosis, certain drug intoxications, and severe diarrhea.
- Atropine sulfate injection is indicated for temporary blockade of severe or life-threatening muscarinic effects, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradyasystolic cardiac arrest.
- Should a patient receive an injectable product containing glass particulate matter as a result of this issue, the patient may experience serious adverse events. Potential complications related to injection of visible and subvisible inert particles include inflammation of a vein, granuloma, and blockage of blood vessels or life-threatening blood clot events. The frequency and severity of these adverse events could vary depending upon a variety of factors including the size and number of particles in the drug product, patient comorbidities, and presence or absence of vascular anomalies.
- To date, Hospira has not received reports of any adverse events related to this recall.
- Anyone with the affected products on hand should discontinue use, stop distribution and quarantine product immediately. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled products.
- Contact Pfizer/Hospira at 1-800-438-1985 or access <u>www.pfizermedinfo.com</u> for questions regarding this recall.

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