

Hospira - Recall of sodium injection and lidocaine injection

- On October 2, 2023, <u>Hospira announced</u> a user-level recall of one lot of <u>sodium bicarbonate</u> injection and two lots of <u>lidocaine hydrochloride</u> injection products because of the potential for presence of glass particulate matter.
- The recalled lots were shipped October 13, 2022 through October 26, 2022.

| Product Description | NDC Number | Lot Number (Exp Date) |
|---|---|--------------------------|
| Sodium bicarbonate 4.2% injection, glass ABBOJECT® syringe, 5 mEq/10mL (0.5 mEq/mL) | Carton: 0409-5534-24; Case: 0409-5534-14 | GJ5007 (8/1/2024) |
| Lidocaine hydrochloride 1% injection, LIFESHIELD® glass ABBOJECT® syringe, 50 mg/5mL (10 mg/mL) | Carton: 0409-4904-11; Case: 0409-4904-34 | 42290DK (6/1/2024) |
| Lidocaine hydrochloride 2% injection, LIFESHIELD® glass ABBOJECT® syringe, 100 mg/5 mL (20 mg/mL) | Carton: 0409-4903-11; Case: 0409-4903-34 | GH6567 (7/1/2024) |

- Sodium bicarbonate injection, is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of hemoglobin and its breakdown products. It is also indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.
- Lidocaine hydrochloride injection is indicated in the acute management of ventricular arrhythmias such as those occurring in relation to acute myocardial infarction, or during cardiac manipulation, such as cardiac surgery.
- There is an unlikely probability for serious adverse events, including death, should a patient receive an injectable product found to contain particulate matter identified as glass. 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 (such as age,
 compromised organ function), and presence or absence of vascular anomalies. The risk is reduced
 by the possibility of detection, as the label contains a clear statement directing the healthcare
 professional to visually inspect the product for particulate matter and discoloration prior to
 administration.
- To date, Hospira, has not received reports of any adverse events associated with this issue for these
 lots.

- Anyone with the affected lot on hand should stop distribution and return product. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Contact Pfizer Medical Information at **1-800-438-1985 (option 3)** or visit **www.pfizermedinfo.com** or Pfizer Drug Safety at **1-800-438-1985 (option 1)** for more information about this recall.



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