COMPANY ANNOUNCEMENT

# SterRx, LLC Issues Voluntary Nationwide Recall of Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL Due to Microbial Contamination



## Summary

**Company Announcement Date:**

August 10, 2021

**FDA Publish Date:**

August 10, 2021

**Product Type:**

Drugs

**Reason for Announcement:**

Due to waterborne microbial contamination

**Company Name:**

SterRx, LLC

**Brand Name:**

SterRx, LLC

**Product Description:**

Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL

## Company Announcement

SterRx, LLC today announced the voluntary nationwide recall of three lots of Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL due to waterborne microbial contamination. SterRx, LLC has initiated this voluntary recall of Sodium Bicarbonate injection, to the Hospital Pharmacy level.

Intravenous administration of Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL, intended to be sterile that is not sterile, could result in site specific infections as well as serious systemic infections which may be life-threatening. To date, SterRx has not

received reports of any adverse events associated with this issue.

Sodium Bicarbonate injection is indicated for the following conditions:

- High Potassium (Hyperkalemia)
- Irregular heartbeat (QRS prolongation ex. tricyclic antidepressant poisoning)
- Metabolic acidosis related to severe renal disease, uncontrolled diabetes, severe primary lactic acidosis, circulatory insufficiency due to shock, severe dehydration, extracorporeal circulation of blood, cardiac arrest, drug toxicities, barbiturates, salicylate, toxic alcohols, urine alkalization, severe diarrhea with $HCO_3$ loss.

The product is supplied in 1000 mL IV bags. The lot numbers being recalled were distributed to hospitals nationwide from May – June 2021.

| Product | NDC Number | Lot Number | Exp. Date | Distribution Dates |
|---|---|---|---|---|
| Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL (12.6 mg per mL) | 70324-326-01 | BUP | 03/23/22 | 06/01/21-06/02/21 |
| | | BUI | 03/16/22 | 05/21/21 – 05/25/21 |
| | | BTW | 03/08/22 | 05/11/21-05/12/21 |

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot of product. The necessary form by which to document this information, as well as other information regarding this recall, is available at www.sterrx.com (http://www.sterrx.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Customers with any questions about returning unused product should be directed to the customer call center at (518) 324-7879, Extension 207 M-F 8:00am to 5:00pm EST. Healthcare workers who have medical questions about Sodium Bicarbonate in 5% Dextrose injection may contact SterRx at (518) 324-7879, Extension 216 M-F 8:00am to 5:00pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

## Company Contact Information

**Consumers:**

Customer Call Center, Medical Affairs

(518) 324-7879, Extension 207, (518) 324-7879, Extension 216

## Product Photos

NDC 70324-**326**-01 **1,000 mL**

# Sodium Bicarbonate

## in 5% Dextrose Injection

## **150 mEq** per 1,000 mL

(12.6 mg per mL)

℞only

**Expiration Date:**
**Compounded On:**
**LOT:**

**Store at Controlled Room Temperature.**

S500050-E

**Sterile Injectable. This is a compounded drug.**
**Not for resale — Hospital/Office use only. Use as directed by authorized practitioner. Do not use if any sign of leakage or precipitate. Product is a clear and colorless to yellow solution. Preservative-free, Latex-free, DEHP-free, PVC-free.**

**Each mL Contains:**

**Active Ingredients:** Sodium Bicarbonate USP 12.6 mg.

**Inactive Ingredients:** 50 mg Dextrose Anhydrous USP, Water for Injection and pH adjusted to 7.0 to 8.5 with Carbon Dioxide.

**Contains:** 1.26% Sodium Bicarbonate in 5% Dextrose Solution for IV Injection.


SterRx®

**141 Idaho Ave.**
**Plattsburgh, NY 12903**
**1-844-319-7799**

**Report suspected adverse events to www.fda.gov/medwatch or 1-800-FDA-1088**

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