DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

B. BRAUN MEDICAL ISSUES VOLUNTARY NATIONWIDE RECALL OF LACTATED RINGER'S INJECTION USP 1000 ML AND 0.9% SODIUM CHLORIDE INJECTION USP 1000 ML DUE TO THE PRESENCE OF PARTICULATE MATTER

8/20/2025

B. Braun Medical Inc. (B. Braun) is voluntarily recalling two lots of Lactated Ringers Injection USP 1000 mL,and 0.9% Sodium Chloride Injection USP 1000 mL to the hospital level due to the presence of particulate matter inside the container.

B. Braun has identified through complaints the potential for the product to contain particulate matter in solution. To date there have been no reports of serious injury, death or other adverse events associated with this issue. If the particulate matter is observed before use, a minor delay could occur while obtaining a replacement product. If the particulate matter is loose and the container is used on a patient, there is a potential for the particulate to be infused into the circulatory system. This could lead to patient harm that may require additional medical intervention and/or lead to permanent impairment or death.

The product has a reasonable probability of causing pulmonary emboli (blockage in pulmonary blood vessels), occlusions of other blood vessels (which can lead to tissue death and possible organ damage), and/or phlebitis (inflammation of the walls of veins, which may lead to clotting). Systemically, foreign particles infused intravenously can cause systemic activation of the immune system, organ dysfunction, and hemolysis (breakdown of blood cells). To date there have been no reports of serious injury, death or other adverse events associated with this issue.

0.9% Sodium Chloride Injection USP is indicated for extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion. Lactated Ringers Injection USP 1000 mL solution is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration. These products are packaged in boxes of 12 each. Additional details on the affected products are as follows:

Product Catalog Number	NDC Number	Product Description	Lot Number	Distribution Range	Expiration Date	Region Distributed
E7500	0264-7750-07	Lactated Ringers Injection USP 1000 mL	J4S807	26DEC2024 - 10APR 2025	31MAY2027	US
E8000	0264-7800-09	0.9% Sodium Chloride Injection USP 1000ML	V3K770	15NOV2023 - 25 SEP2024	31JAN2026	US

These products were distributed nationwide via distributors.

B. Braun is notifying its distributors and customers by certified mail and is arranging for return. of all recalled products. Distributors that have affected product which is being recalled should determine their current inventory of the affected items within inventory of their facility, cease use and distribution and quarantine product subject to recall. Affected product should not be destroyed.

Customers who have questions about this recall should contact our B. Braun's Recalls Department at 844-903-6417 between 9 AM and 5 PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug 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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-medical-issues-voluntary-nationwide-recall-lactated-ringers-injection-usp-1000-ml-and-09?utm_medium=email&utm_source=govdelivery

Company Contact Information

Consumers:

B. Braun's Recalls Department

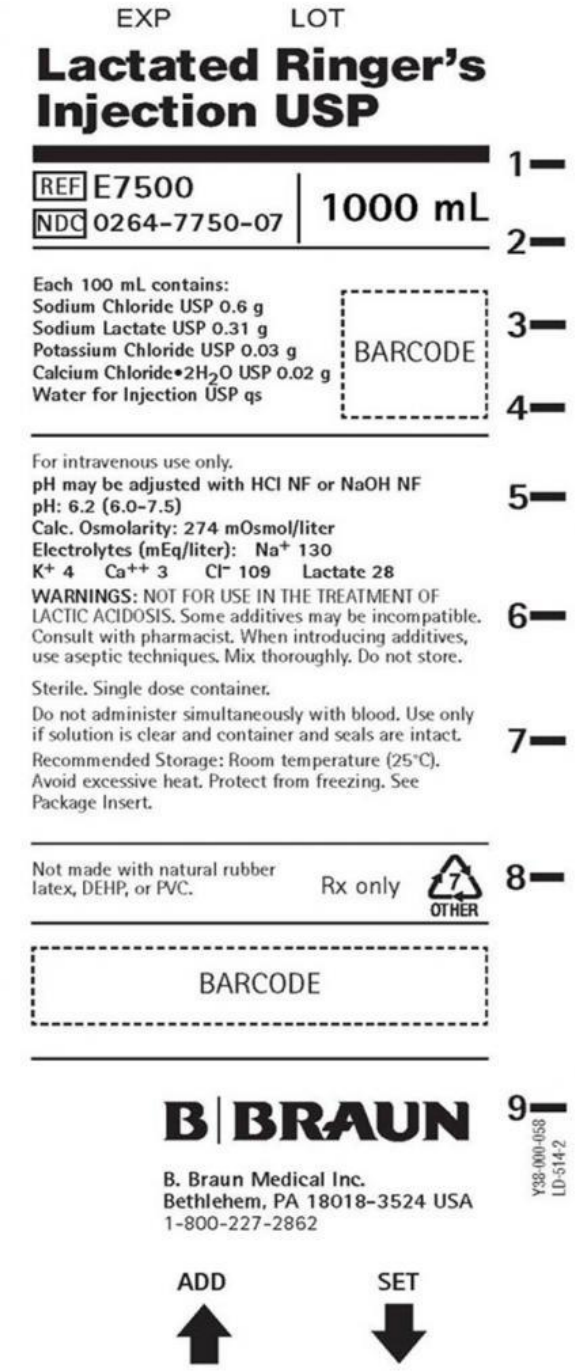
844-903-6417

Media:

484-523-9801

allison.longenhagen@bbraunusa.com

Product Photos


EXP
LOT
Lactated Ringer's Injection USP
REF E7500
NDC 0264-7750-07
1000 mL
Each 100 mL contains:
Sodium Chloride USP 0.6 g
Sodium Lactate USP 0.31 g
Potassium Chloride USP 0.03 g
Calcium Chloride•2H2O USP 0.02 g
Water for Injection USP qs
BARCODE
For intravenous use only.
pH may be adjusted with HCl NF or NaOH NF
pH: 6.2 (6.0-7.5)
Calc. Osmolarity: 274 mOsmol/liter
Electrolytes (mEq/liter): Na+ 130
K+ 4 Ca++ 3 Cl- 109 Lactate 28
WARNINGS: NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.
Sterile. Single dose container.
Do not administer simultaneously with blood. Use only if solution is clear and container and seals are intact.
Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.
Not made with natural rubber latex, DEHP, or PVC.
Rx only
7
OTHER
BARCODE
B BRAUN
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
Y38-000-058
LD-514-2
ADD
SET
1
2
3
4
5
6
7
8
9