

URGENT: DRUG RECALL – Sterile Injectable

RE: 23.4% Sodium Chloride Injection, Lots 210137-01, 220026-01, and 220050-01

FOR IMMEDIATE RELEASE –April 1, 2022 – Columbia, SC, The Ritedose Corporation is voluntarily recalling 23.4% Sodium Chloride Injection (120 mEq/30 mL) supplied in a 50 mL pre-filled syringe to the hospital/office level. The product has been found to be labeled with an incorrect NDC barcode. The barcode is incorrectly coded with NDC 65302-510-10 which is for Rocuronium Bromide Injection (100 mg per 10 mL) supplied in a 10 mL pre-filled syringe. The barcode should be coded with NDC 65302-509-30 for 23.4% Sodium Chloride Injection. Please note that the human readable NDC printed on the syringe label is correct as well as all other components of the syringe label. The incorrect NDC coded in the barcode could result in administration errors, and therefore represents a potential health hazard. The Ritedose Corporation has not received any reports of adverse events related to this recall.

The product was distributed to hospitals nationwide. Please examine your stocks immediately to determine if you have lots 210137-01, 220026-01, and 220050-01 on hand. If so, please discontinue dispensing the lot and promptly return via parcel post, to the following address:

ATTENTION: RECALL PROCESSING - George Hutton
The Ritedose Corporation
1 Technology Circle
Columbia, SC 29203

You will be reimbursed for the returned goods and postage. If you have any questions about returning product or reimbursement, please contact recall@ritedose.com (M-F 8am-5pm EST).

Please return the enclosed recall return reply request letter immediately providing the requested information.

This recall is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.



Jody Chastain
President and CEO

RECALL RETURN REPLY REQUEST LETTER

Dear Valued Customer,

Please complete the following information and return to Ritedose by e-mail to recall@ritedose.com or by using the pre-paid FedEx label enclosed.

[] We do not have any stock of **23.4% Sodium Chloride Injection** on hand.

[] We have the following stock of **23.4% Sodium Chloride Injection** on hand*:

Lot:	Quantity:
210137-01	_____ pre-filled syringes
220026-01	_____ pre-filled syringes
220050-01	_____ pre-filled syringes

Company Name _____

Contact Name / Title _____

Address _____

City _____ State _____ Zip Code _____

*Please return all remaining stock to the following:

ATTENTION: RECALL PROCESSING - George Hutton
The Ritedose Corporation
1 Technology Circle
Columbia, SC 29203

You will be reimbursed for the returned goods and postage.