COMPANY ANNOUNCEMENT

SCA Pharmaceuticals (SCA) Is Issuing a Voluntary Nationwide Recall of Heparin Sodium Compounded Products Due to Incorrect Preservative (Benzyl Alcohol)

Summary

Company Announcement Date:

August 18, 2020

FDA Publish Date:

August 18, 2020

Product Type:

Drugs

Reason for Announcement:

Incorrect preservative (benzyl alcohol)

Company Name:

SCA Pharmaceuticals

Brand Name:

SCA Pharma

Product Description:

Heparin Sodium Compounded products

Company Announcement

Windsor, CT, SCA Pharmaceuticals (SCA) is voluntarily recalling 10 lots of Heparin Sodium to the hospital/user level. The compounded Heparin Sodium bag contains the undeclared preservative benzyl alcohol. The labelling listed methylparaben and propylparaben as preservatives; however, are not present in the product. SCA identified this labeling issue during the investigation of a low potency test result for Heparin Sodium (NDC 70004-0650-46).

Serious adverse reactions including fatal reactions and "gasping syndrome" are likely to occur in premature neonates and low-birth weight infants in the neonatal intensive care unit who receive benzyl alcohol as a preservative in infusion solutions, in any amount. Additional adverse reactions included gradual nervous system deterioration, seizures, bleeding in the skull, blood abnormalities, skin breakdown, liver and kidney failure, low blood pressure, slower than expected heart rate, and loss of sufficient brain blood flow to maintain consciousness. Preterm, low-birth weight infants may be more likely to develop these reactions because they may be less able to metabolize benzyl alcohol. Furthermore, benzyl alcohol present in mother's serum is likely to cross into human milk and may be orally absorbed by a nursing infant. For this reason, preservative-free heparin sodium injections is recommended when heparin therapy is needed during pregnancy. Benzyl alcohol is contraindicated in pediatric patients as well as pregnant or nursing women. SCA has not received any complaints or reports of adverse events to date related to this recall. However, out of an abundance of caution, SCA is voluntarily recalling the lots listed herein.

Heparin Sodium is used as an anticoagulant and is packaged in 500 mL or 1000 mL intravenous bags. The affected Heparin Sodium lots include the following:

Product Description	NDC Number	Lot Number	Beyond Use Date
Heparin Sodium 10 units/mL in 0.9% Sodium Chloride 500 mL Bag (5,000 units/500 mL)	70004-0650-44	1220019289	8/21/2020
Heparin Sodium 5 units/mL in 0.9% Sodium Chloride 500 mL Bag (2,500 units/500 mL)	70004-0655-44	1220019269	8/21/2020
		1220019278	8/21/2020
		1220019386	8/25/2020
Heparin Sodium 10 units/mL in 0.9% Sodium Chloride 1,000 mL Bag (10,000 units/1,000 mL)	70004-0652-46	1220019457	8/24/2020
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000mL Bag (5 units/mL)	70004-0650-46	1220019243	8/20/2020
		1220019439	8/24/2020
		1220019279	8/24/2020
		1220019392	8/24/2020
		1220019488	8/26/2020

The compounded Heparin Sodium can be identified by checking the product name, concentration and lot number on the compounded bag. The compounded Heparin Sodium bags were distributed nationwide to hospitals.

SCA is notifying its customers by certified mail and is arranging for return of all recalled products. Hospitals that have compounded Heparin Sodium bags which are being recalled should stop using the product and return the product to SCA.

Consumers with questions regarding this recall can contact SCA by phone at 877-550-5059 or e-mail customerservice@scapharma.com (mailto:customerservice@scapharma.com) between the hours of 7:00 am and 7:00 pm (Central Standard Time), Monday through Friday. 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 (/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:

SCA

877-550-5059

customerservice@scapharma.com (mailto:customerservice@scapharma.com)

Product Photos

HIGH ALERT MEDICATION

Heparin Sodium

5,000 units

in 0.9% Sodium Chloride 500 mL

Injection for Intravenous Use
(Concentration = 10 units/mL)

Store at Room Temperature
Protect from Light

70004065044

LOT:

Use By:
MM/DD/YYYY

Compound Date: MM/DD/YYYY

Each mL Contains:

heparin sodium 10 units, sodium chloride for isotonicity, methylparaben 0.015 mg, propylparaben 0.0015 mg, water for injection, pH adjusted with hydrochloric acid and/or sodium hydroxide

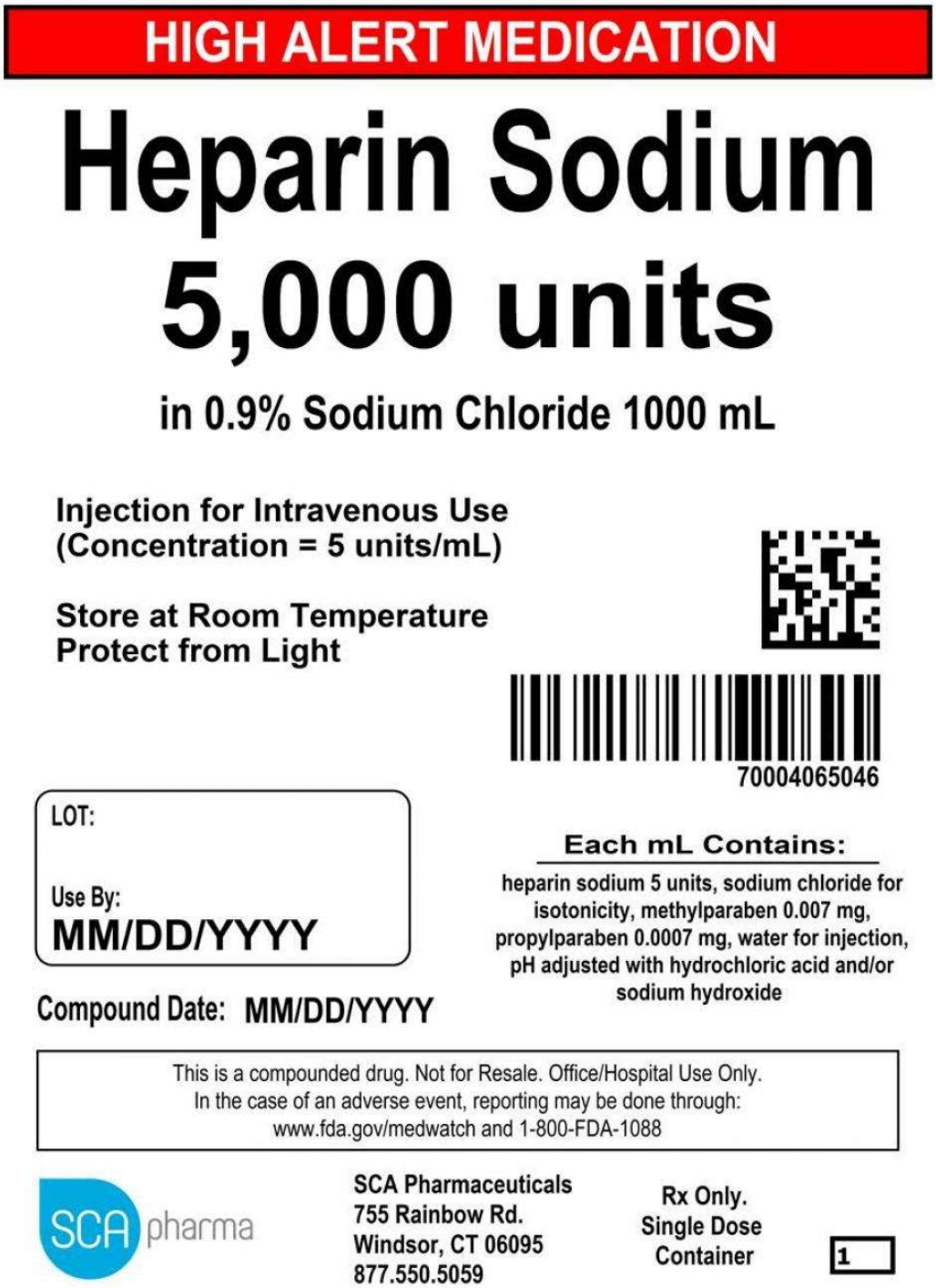
This is a compounded drug. Not for Resale. Office/Hospital Use Only.
In the case of an adverse event, reporting may be done through:
www.fda.gov/medwatch and 1-800-FDA-1088

SCA pharma

SCA Pharmaceuticals
755 Rainbow Rd.
Windsor, CT 06095
877.550.5059

Rx Only.
Single Dose Container

1


HIGH ALERT MEDICATION
Heparin Sodium
5,000 units
in 0.9% Sodium Chloride 1000 mL
Injection for Intravenous Use
(Concentration = 5 units/mL)
Store at Room Temperature
Protect from Light
70004065046
LOT:
Use By:
MM/DD/YYYY
Each mL Contains:
heparin sodium 5 units, sodium chloride for isotonicity, methylparaben 0.007 mg, propylparaben 0.0007 mg, water for injection, pH adjusted with hydrochloric acid and/or sodium hydroxide
Compound Date: MM/DD/YYYY
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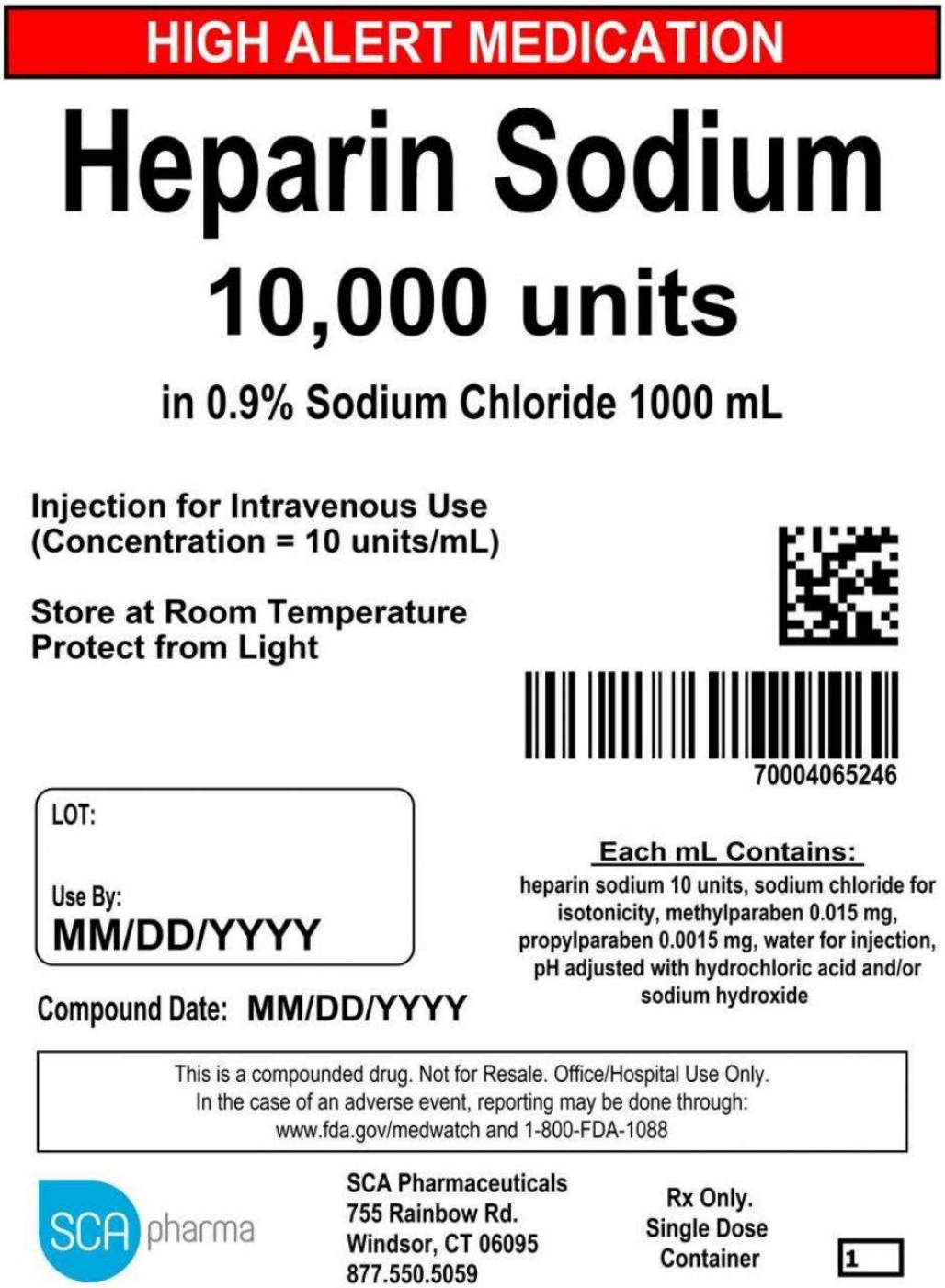
HIGH ALERT MEDICATION
Heparin Sodium
10,000 units
in 0.9% Sodium Chloride 1000 mL
Injection for Intravenous Use
(Concentration = 10 units/mL)
Store at Room Temperature
Protect from Light
70004065246
LOT:
Use By:
MM/DD/YYYY
Each mL Contains:
heparin sodium 10 units, sodium chloride for isotonicity, methylparaben 0.015 mg, propylparaben 0.0015 mg, water for injection, pH adjusted with hydrochloric acid and/or sodium hydroxide
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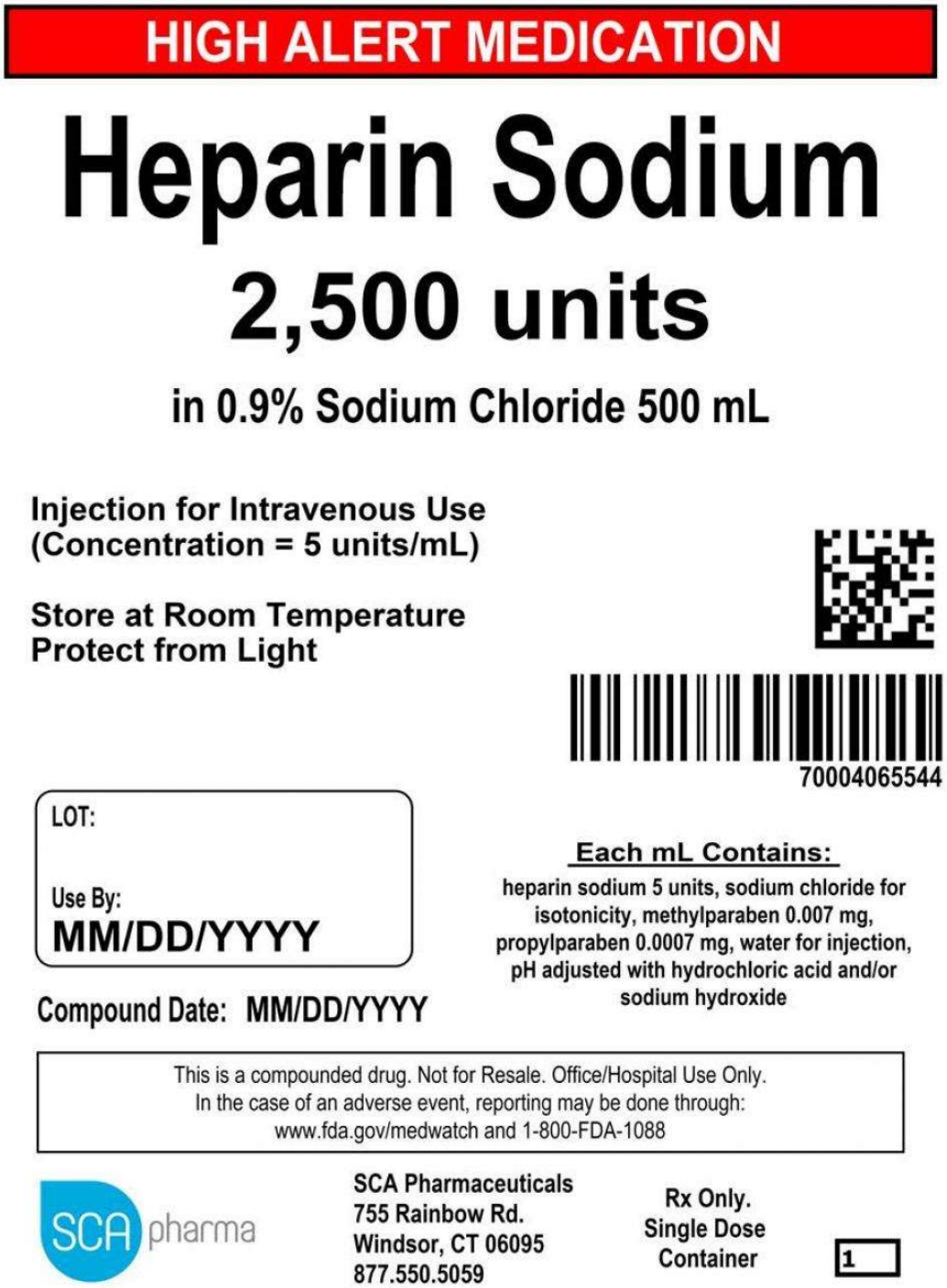

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)