RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Heparin Sodium Compounded Products Recall Alert

Date of Notice: 08/18/2020

Brief Description of Recall Alert

SCA Pharmaceuticals (SCA) is voluntarily recalling 10 lots of heparin sodium. The compounded heparin contains the undeclared preservative benzyl alcohol. The labeling listed methylparaben and propylparaben as preservatives; however, these are not present in the product. SCA identified this labeling issue during the investigation of a low potency test result.

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 include 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 are recommended when heparin therapy is needed during pregnancy. Benzyl alcohol is contraindicated in pediatric patients as well as pregnant or nursing women.

Heparin sodium is used as an anticoagulant and is packaged in 500 mL or 1000 mL intravenous bags.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration 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 1220019278	8/21/2020
heparin sodium 5 units/mL in 0.9% sodium chloride 500 mL Bag (2,500 units/500 mL)	70004-0655-44	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

heparin sodium 5,000 units in 0.9% sodium chloride 1000mL Bag (5 units/mL)	70004-0650-46	1220019279 1220019392 1220019439	8/24/2020
heparin sodium 5,000 units in 0.9% sodium chloride 1000mL Bag (5 units/mL)	70004-0650-46	1220019488	8/26/2020

Prescriber Information

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. 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.

Adverse reactions or quality problems experienced with the use of this drug should 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
- Regular Mail or Fax: Download form 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

Member Information

Consumers with questions regarding this recall can contact SCA by phone at 877-550-5059 or e-mail customerservice@scapharma.com between the hours of 7:00 am and 7:00 pm (Central Standard Time), Monday through Friday. Members should contact their doctor if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall. RxAdvance recommends that you speak to your doctor if you have experienced any of the listed adverse reactions.