Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

SCA Pharmaceuticals Issues Voluntary Nationwide Recall of Specific Products Due to Potential Contamination

For Immediate Release

October 20, 2017

Contact

Consumers

SCA Pharmaceuticals
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Media

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Announcement

SCA Pharmaceuticals LLC (“SCA Pharmaceuticals”) is voluntarily recalling all/the following lots of the below listed injectable products to the hospital level. The is a potential for the products to contain microbial contamination.

Administration of a drug product, intended to be sterile, that may contain microbial contamination has the potential to result in serious adverse events which may include life-threatening infections. SCA Pharmaceuticals has not received any customer complaints or reports of adverse events related to this issue, but out of an abundance of caution, is voluntarily initiating this recall.

Product Name	Product Number	Type of Packaging	Indication	SCA Lot Number	Beyond Use Date	Quantity Shipped	Date(s) Distributed
Succinylcholine Chloride 20 mg/mL 10 mL syringe	70004-0910-29	Rigid plastic syringe, 10mL	Skeletal muscle relaxant	20170726@35	10/24/2017	1248	07/27/2017 - 07/28/2017
Hydromorphone 1 mg/mL in 25 mL 0.9% Sodium Chloride	70004-0303-17	Rigid plastic syringe, 30mL	Analgesic	20170808@52	11/06/2017	128	08/09/2017
Fentanyl 2 mcg/mL + Bupivacaine 0.125% in 250 mL 0.9% Sodium Chloride	70004-0231-40	Flexible plastic IV bag, 250mL	Analgesic	20170814@20	11/12/2017	116	08/16/2017 – 08/25/2017
Hydromorphone 20 mcg/mL + Bupivacaine 0.075% in 50 mL 0.9% Sodium Chloride	70004-0331-22	Flexible plastic IV bag, 50mL	Analgesic	20170816@65	10/30/2017	60	08/18/2017
Morphine 1 mg/mL in 50 mL 0.9% Sodium Chloride	70004-0100-22	Flexible plastic IV bag, 50mL	Analgesic	20170901@25	11/30/2017	238	09/06/2017 – 09/27/2017

Morphine 1 mg/mL in 100 mL 0.9% Sodium Chloride (CADD)	70004-0100-63	Flexible plastic bag inside rigid translucent plastic case (CADD), 100mL	Analgesic	20170905@24	12/04/2017	60	09/06/2017 – 09/18/2017
Oxytocin 30 units added to 500 mL Lactated Ringers	70004-0086-44	Flexible plastic IV bag, 500mL	Precipitate Labor	20170912@13	10/22/2017	450	09/13/2017 – 09/14/2017
Phenylephrine 100 mcg/mL 10 mL in 12 mL syringe	70004-0810-12	Rigid plastic syringe, 12mL	Hypotension	20170920@53	12/19/2017	1221	09/22/2017

Product Name	Product Number	Type of Packaging	Indication	SCA Lot Number	Beyond Use Date	Quantity Shipped	Date(s) Distributed
Fentanyl 2 mcg/mL (as citrate) Ropivacaine HCl 0.1%	70004-0264-64	Flexible plastic bag inside rigid translucent plastic case (CADD), 100mL	Analgesic	20170815@26	11/13/2017	20	08/17/2017
Calcium Gluconate 2 g added to 50 mL 0.9% Sodium Chloride	70004-0510-30	Flexible plastic IV bag, 50mL	Hypocalcemia	20170920@20	11/09/2017	76	9/26/2017

Rocuronium 10 mg/mL 5 mL in 6 mL syringe	70004-850-09	Rigid plastic syringe, 6mL	Skeletal muscle relaxant	20171004@4	01/09/2018	487	10/05/2017

These injectable products' indicated use and package type are identified in the above table. The affected product lots are also included in the table above. The product can be identified by the attached labels. The products associated with this recall were distributed nationwide to hospitals.

SCA Pharmaceuticals is notifying its customers via telephone, email and US mail and is arranging for return/replacement of all recalled products. Customers that have product which is being recalled, as indicated in the list above, should discontinue use immediately and return the product to SCA Pharmaceuticals at the address below.

SCA Pharmaceuticals
8821 Knoedl Court Little Rock, AR 72205

Consumers with questions regarding this recall can contact SCA Pharmaceuticals at 877-550-5059, between the hours of 8:00 am and 5:00 pm (Central Standard Time), Monday thru 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: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://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 Food and Drug Administration.

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