



California Dialysis Council

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NEWS UPDATE

FDA MedWatch-Sodium Polystyrene Sulfonate Suspension- Recall Of 2 Lots Of Product Due To The Presence Of Yeast Which Could Affect Immunocompromised Patients

Roxane Laboratories, Inc. informed healthcare professionals of the recall of two lots of Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles (NDC 0054-0165-51; lot 856396A Exp April 2010, and lot 856693A Exp May 2010), a product used to treat hyperkalemia. A sample of one of the affected lots tested positive for a strain of yeast, which could potentially affect immunocompromised patients. Symptoms of a yeast infection range from thrush, skin rash, and blood infections. If patients develop an infection they should consult their physician. Pharmacists should determine if any of the referenced product has been dispensed and retrieve it. Additionally, pharmacists and wholesalers of the product should discontinue distribution and use of the referenced lots immediately and contact the manufacturer regarding returning the product.

See the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's recall notice regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#SPSS>.



Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Roxane Laboratories, Inc. Initiates a Nationwide Voluntary Recall of Two Manufacturing Lots of Sodium Polystyrene Sulfonate Suspension in the US and Puerto Rico

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FOR IMMEDIATE RELEASE -- Columbus, Ohio -- July 14, 2008 -- Roxane Laboratories, Inc. announced today that it is conducting a nationwide voluntary recall of two manufacturing lots of Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles (NDC 0054-0165-51; Lot 856396A Exp April 2010, and Lot 856693A Exp May 2010). Sodium Polystyrene Sulfonate Suspension is used to treat hyperkalemia (an elevated blood level of the electrolyte potassium).

Roxane Laboratories' number one priority is for the safety of patients who use our products. A sample from product lot 856396A tested positive for a strain of yeast, which could potentially affect immunocompromised patients. Roxane Laboratories believes that this may be attributed to yeast contamination in one lot of high-density polyethylene bottles received from a supplier. There are various manifestations of yeast infections. The risk of developing a yeast infection depends on how immunocompromised the patient is. Additionally, there are a range of symptoms in a yeast infection from thrush, skin rash, and blood infections (sepsis). If patients develop an infection they should consult their physician. Due to the potential risks that could occur in immunocompromised patients, Roxane Laboratories is voluntarily recalling lot 856396A. Although there have been no testing failures associated with lot 856693A, this additional lot is also being included in the recall as a precautionary measure because the same lot of bottles was used in both finished product lots. All other product parameters were within specification and product efficacy is not impacted. There have been no complaints or adverse events reported for the affected lots. This recall is limited to the two lot numbers listed.

No other Roxane Laboratories, Inc. products or lots are impacted by this recall.

Information has been sent to Pharmacists alerting them of the details pertaining to this recall. As described in these recall communications, pharmacists who may have dispensed Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles from Lots 856396A and 856693A are instructed to contact those patients to return the affected product to the pharmacist.

Pharmacists and wholesalers that have any Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles from Lot 856396A or Lot 856693A have been instructed to discontinue distribution and use of these lots immediately and contact Capital Returns at 888.839.7837 for any questions regarding the recall returns. Requests for additional information should be referred to Roxane Laboratories Technical Product Information at 800.962.8364.

Advice For Patients Taking Sodium Polystyrene Sulfonate Suspension USP, 15 g/60 mL Unit Dose Bottles

If your pharmacist has notified you that you may have received a bottle from one of the lots listed in this recall, please return your Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles to your pharmacist.

If you have NOT been notified by your pharmacist, please check your product to determine if it is from either of the two affected lots: Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 mL Unit dose bottles from Lot 856396A Exp April 2010, or Lot 856693A Exp May 2010. If the product has either of these two lot numbers on the bottle, please contact your pharmacist for further instructions. This recall has been limited to these two specific lots.

Roxane Laboratories is working with the US FDA on this voluntary recall. The products discussed in this press release are available by prescription only, and no injuries have been reported in relation to this issue.