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.

Fagron Sterile Services Issues Voluntary Nationwide Recall of Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL and Neostigmine Methylsulfate 1mg/mL, 3mg per 3mL, in a 5mL syringe Due to Mislabeling

For Immediate Release

June 29, 2018

Contact

Consumers

1-877-405-8066

Announcement

Fagron Sterile Services is voluntarily recalling two (2) lots of Neostigmine Methylsulfate 5mL syringes to the user/hospital/clinic level. The specified product lots are being recalled because of a confirmed customer complaint that some syringe units containing Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL are incorrectly labelled as Neostigmine Methylsulfate 1mg/mL, 3mg per 3mL. Secondary packages are properly labelled as Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL.

Risk Statement: In the event that 5mL rather than the intended 3mL is administered to a patient, adverse events from Neostigmine Methylsulfate overdosage can range from nausea, vomiting, diarrhea, excessive salivation and sweating, increased bronchial secretions, miosis, bradycardia or tachycardia, cardiospasm, bronchospasm,

incoordination, muscle cramps, fasciculation, paralysis, to Cholinergic Crisis resulting in death. To date, Fagron has not received any reports of adverse events or injuries related to this recall.

Neostigmine Methylsulfate Injection, USP is a cholinesterase inhibitor indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery supplied by Fagron Sterile Services in a single-use syringe and is produced by Fagron Sterile Services into 5mL or 3mL fill presentation of 1 mg/mL of Neostigmine Methylsulfate. The impacted product Neostigmine Methylsulfate 1mg/mL can be identified by the following:

Lot Number	Item Description	NDC #	Beyond-Use Date
C274-000004690	Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL (API)	71266-2003-02	09-21-18
C274-000004678	Neostigmine Methylsulfate 1mg/mL, 3mg per 3mL, 5mL syringe (API)	71266-2003-01	09-20-18

The impacted lots were distributed nationwide directly to hospitals and surgical clinics. Fagron Sterile Services has notified its direct customers by telephone and is arranging for return and replacement of all recalled products. Hospitals or surgical clinics that have received impacted product should immediately examine stock and discontinue dispensing. Promptly contact Stericycle to arrange product return at 1-888-918-8756, from Monday to Friday, 8:00am to 5:00pm EDT for instructions on how to return impacted product. Healthcare professionals which have the Neostigmine Methylsulfate products which are being recalled should stop use and return to Fagron Sterile Services.

Consumers with questions regarding this recall can contact Fagron Sterile Services by phone at 1-877-405-8066 M-F 8:00am – 5:00pm CDT. 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**: **http://www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
• **Regular Mail or Fax**: Download form **http://www.fda.gov/MedWatch/getforms.htm o (http://www.fda.gov/MedWatch/getforms.htm)**r 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.

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