SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

NEW DRUG FAX SHEET

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NATIONWIDE RECALL OF SEVERAL LOTS OF ATRACURIUM BESYLATE INJECTION

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding a voluntary national recall of several lots of atracurium besylate injection (manufactured by Emcure Pharamcetuicals Ltd and distributed by Sagent) due to issues associated with product sterility. The verbatim safety alert can be found below. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Emergency Medicine, Anesthesiology, Risk Manager

ISSUE: Sagent Pharmaceuticals, Inc. announced the voluntary nationwide recall of two lots of Atracurium Besylate Injection, USP, 50mg/5mL single-dose vials (NDC 25021-659-05) and four lots of Atracurium Besylate Injection, USP, 100mg/10mL multi-dose vials (NDC 25021-672-10) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Sagent. Sagent has initiated this voluntary recall of Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.

Non-sterility of a drug administered via the intravenous route has the potential to result in infections, which could be fatal, especially in patients who are immunocompromised.

BACKGROUND: The lot numbers being recalled are VATA012, VATA015 (50mg/5mL) and VATB012, VATB013, VATB014, VATB017 (100mg/10mL) which were distributed to hospitals, wholesalers and distributors nationwide from February 2014 through February 2015 and are supplied in single-dose and multi-dose vials.

Sagent has transferred the manufacture of this product to its own facility and this product manufactured at the Sagent facility will not be impacted by the recall.

RECOMMENDATION: Customers are instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Atracurium Besylate Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- 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

Read the MedWatch Safety Alert, including links to the Press Release at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm435440.htm

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