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Pharmacy Safety Alert

March 1, 2016

Sagent Pharmaceuticals Initiates a Nationwide Voluntary Recall of Fluconazole Injection, USP, (in 0.9% Sodium Chloride) 200mg per 100ml Due to the Discovery of an Out of Specification Impurity Result Detected During Quality Testing

SCHAUMBURG, IL – Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of one lot of Fluconazole Injection, USP, (in 0.9% Sodium Chloride) 200mg per 100mL flexible container bag (NDC 25021-113-82) Lot 40608 manufactured by ACS Dobfar INFO S.A. and distributed by Sagent. Sagent has initiated this voluntary recall of Fluconazole Injection, USP, 200mg per 100mL to the user level due to the discovery of an out of specification impurity result detected during routine quality testing of stability samples at the 18-month interval. This impurity has been identified as Metronidazole. An elevated impurity has the potential to decrease effectiveness of the product in patients. Patients on the product and on concomitant medication of Metronidazole may receive an increased dose of Metronidazole.

Sagent is not aware of any adverse patient events resulting from the use of the subject product lot.

The lot number being recalled is Lot 40608 which was distributed to hospitals, wholesalers and distributors nationwide from November 2014 through December 2014. Fluconazole Injection, USP, 200mg per 100mL is indicated, for the treatment of Oropharyngeal and esophageal candidiasis, cryptococcal meningitis, and is supplied in 100mL and 200mL flexible container bags.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot 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.

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 Fluconazole Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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
    - **Regular Mail or Fax:** Download form 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 U.S. Food and Drug Administration.