



SAGENT™

Sagent Pharmaceuticals, Inc.

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Dear Healthcare Professional:

SUBJECT: Recall of Amiodarone Hydrochloride Injection 150 mg/3 ml (NDC 25021-302-73)

Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of all lots of Amiodarone Hydrochloride Injection 150 mg/3 ml (NDC 25021-302-73) distributed by Sagent Pharmaceuticals, Inc.. The lot numbers being recalled are: ER001, ER002, ER003, ER004, ER005, ER006, ER007, ER008, ER009, and ER010, which were distributed to hospitals, wholesalers and distributors nationwide from April 2010 to March 2011.

Sagent has initiated this voluntary recall to the user level due to reports of incompatibility of certain needleless I.V. sets with Luer-Activating Devices with Sagent's Amiodarone Pre-filled Syringes, resulting in adverse events.

Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return all recalled lots of the 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) 946-4679. Healthcare workers who have medical questions about Amiodarone Hydrochloride Injection may contact Sagent Medical Affairs (866-625-1618 option 3). Due to this issue, Amiodarone Pre-Filled Syringes will not be available, until such time as the problem is resolved.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program by fax at 1-800-fda-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787 or on the MedWatch website at www.fda.gov/safety/medwatch/default.htm.

Sincerely,

Igoni Dokubo, M.D.
Medical Director
Sagent Pharmaceuticals, Inc.