



SAGENT™

Sagent Pharmaceuticals, Inc.

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November 23, 2010

Dear Customer

**SUBJECT: Product-Connector Incompatibility and FDA Communications Regarding  
Sagent's Adenosine Injection, USP and Amiodarone HCl Injection  
Prefilled Syringes**

In response to the recent FDA teleconference and website posting regarding Prefilled Syringe compatibility with certain needleless I.V. sets with Luer-Activated Devices (LADs), Sagent would like to share additional information regarding our products. As the result of product-connector compatibility concerns with our Adenosine Injection, USP and Amiodarone HCl Injection syringes, Sagent have taken the following actions:

In cooperation with the FDA

1. We issued a "Dear Healthcare Professional" letter that has been and continues to be available on our website since July, 2009.
2. We revised product labeling to include a "Caution: Product-Connector Incompatibility Notice" on the primary and secondary cartons and in the package insert. All products being distributed from Sagent's warehouse features the updated labeling with the cautionary statement. Some wholesalers may have older inventory to deplete prior to distributing product with the updated labeling. Please see attached Exhibit for a sample of the labeling statements.

Additionally, we immediately began investigating alternative syringes. We are optimistic that we will have a solution that will eliminate the product connector issues.



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The Sagent products impacted by the Product-Connector Incompatibility issue are the following:

<b>NDC</b>	<b>Product</b>	<b>Strength</b>
25021-301-72	Adenosine Injection, USP	6 mg per 2 mL
25021-301-76	Adenosine Injection, USP	12 mg per 4 mL
25021-302-73	Amiodarone HCL Injection	150 mg per 3 mL

We are working closely with the FDA to communicate this important safety information. Should you have further questions and concerns, we encourage you to contact us directly either through our Medical Affairs Department at 1-866-625-1618 option 3 or visit our website [www.SagentPharma.com](http://www.SagentPharma.com).

Sincerely,

Lorin J. Drake  
Vice President of Sales and Marketing  
Sagent Pharmaceuticals, Inc.

Enclosures 3



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EXHIBIT – Page 1 of 2

**Inner Carton**

**Front of Carton**

**CAUTION: Product-Connector Incompatibility Notice:**  
See Dosage and Administration section of the package insert.


**Back of Carton**

**CAUTION: Product-Connector Incompatibility Notice:**  
Certain Needleless IV sets with Luer-Activated Devices (LADs) may be incompatible with this syringe. See Dosage and Administration section of the package insert.



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EXHIBIT – Page 2 of 2

<p><b>Package Insert</b></p>	<p><b>Outer Carton</b></p>
<p><b>CAUTION: Product-Connector Incompatibility Notice:</b>          Certain Needleless IV sets with Luer-Activated Devices (LADs) may be incompatible with this syringe. Some LADs that are incompatible with this syringe include the Hospira LifeShield™ Clave® and LifeShield™ Micro-Clave®, ICU Medical Clave® and Micro-Clave®, the Rymed Invision-Plus® Neutral® IV Connector, and the Vygon Bionector®. These LADs were designed to require a syringe inner luer tip diameter that is larger than that of these or any other commonly used glass syringes. While the Adenosine syringes may be connected to these LADs successfully, the physical incompatibility caused by the luer tip diameter significantly impairs or even prevents administration of the drug.</p> <p><b>HOW SUPPLIED</b>          Adenosine Injection USP is supplied as a sterile solution in normal saline as follows:</p>	 <p>The image shows the outer carton for Adenosine Injection USP. It features three columns, each representing a syringe. Each syringe is labeled 'Adenosine Injection, USP' and '6 mg per 2 mL'. The syringes are for 'Rapid Bolus Intravenous Use' and are 'SINGLE-USE PREFILLED SYRINGES'. The carton also includes a barcode, lot number, and expiration date information.</p>
<p><b>CAUTION: Product-Connector Incompatibility Notice:</b>          Certain Needleless IV sets with Luer-Activated Devices (LADs) may be incompatible with this syringe. Some LADs that are incompatible with this syringe include the Hospira LifeShield™ Clave® and LifeShield™ Micro-Clave®, ICU Medical Clave® and Micro-Clave®, the Rymed Invision-Plus® Neutral® IV Connector, and the Vygon Bionector®. These LADs were designed to require a syringe inner luer tip diameter that is larger than that of these or any other commonly used glass syringes. While the Amiodarone syringes may be connected to these LADs successfully, the physical incompatibility caused by the luer tip diameter significantly impairs or even prevents administration of the drug.</p>	