GILEAD
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URGENT DRUG RECALL: VISTIDE®

February 7, 2013

Dear Healthcare Provider,

This is to provide you with additional information related to the following product recall, for which you received an alert on February 4, 2013. As a reminder, Gilead Sciences, Inc. is voluntarily recalling Vistide® (cidofovir injection) Lot # B120217A.

Product Description	NDC	Lot #	Expiration Date
Vistide® (cidofovir injection)	61958-0101-1	B120217A	May 2015

See product label for ease in identifying the product at the user level:
http://www.gilead.com/pdf/vistide.pdf

This voluntary recall is being conducted because particulate matter was found in some vials during packaging operations. Effects from intravenous injection of product with particulate matter can vary depending on the amount of particulate matter injected into the patient, the size of the particles, and the patient's underlying medical condition. Effects can range from no detectable clinical morbidity to allergic/anaphylactic reaction, tissue necrosis in one or more organs, stroke, myocardial infarction, respiratory failure, and loss of renal or hepatic function; which could result in death. An investigation has been initiated to identify the particles and determine the extent of the problem. Gilead is not currently aware of any complaint attributable to the particles; however, recognizing the possible seriousness of the situation, Gilead is recalling Vistide to the user level; the recall is limited only to the specific lot listed above.

We began shipping this lot of Vistide to wholesaler/distributors starting October 2012.

ACTION REQUIRED:

1. **Check your inventory and immediately quarantine any Vistide product with the lot number referenced above.**

2. **Stop dispensing the recalled lot immediately.**

3. **If you may have further distributed this lot, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this alert.**

4. **If you have Vistide product with the lot number referenced above, call Stericycle at 1-888-965-5791, Monday to Friday 8:00 a.m. to 8:00 p.m. Eastern Time, for information on how to return the product.**

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA www.gilead.com
phone 650 574 3000 *facsimile* 650 578 9264

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent patient harm.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

OTHER INFORMATION:

Vistide (cidofovir injection) is indicated for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS). There are other drugs used for the treatment of CMV retinitis including but not limited to, intraocular ganciclovir implant, oral valganciclovir, ganciclovir, and foscarnet.

There have been no product complaints received in the past twelve months for Vistide in all markets. Gilead has initiated a targeted analysis of its global safety database to specifically identify any potential signals that may be related to particles and/or contamination in Vistide (cidofovir injection).

Gilead is currently conducting a review of the supply of Vistide. At the present time, there are no available lots of Vistide in the supply chain to replace the affected lot. In the United States, healthcare providers may explore other manufacturing sources for cidofovir.

For medical questions contact Gilead Sciences Medical Information at **1-800-GILEAD-5 (1-800-445-3235) [Option 2].**

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Sincerely,

Hans Reiser, MD
Senior Vice President, Medical Affairs
Gilead Sciences, Inc.