SANDOZ
a Novartis company

March 1, 2016

Dear Healthcare Professional:

Due to the current critical shortage of L-Cysteine Hydrochloride Injection in the U.S., Sandoz is temporarily importing Sandoz Canada's L-Cysteine Hydrochloride Injection into the U.S. market. At this time, FDA is not objecting to the importation and distribution of Sandoz Canada's L-Cysteine for Injection to address the U.S shortage of this product. There are currently no FDA-approved L-Cysteine Hydrochloride Injection products in the United States.

This imported Sandoz Canada's L-Cysteine Hydrochloride Injection, 50 mg/mL product contains the same active ingredient, L-Cysteine Hydrochloride Monohydrate USP, as the L-Cysteine Hydrochloride Injection, 50 mg/mL product currently marketed in the United States. Healthcare providers, however, should be aware of certain differences between the U.S. product and the Sandoz Canada product before prescribing and preparing the product.

Labeling Property	**L-Cysteine Hydrochloride Injection manufactured for Sandoz in U.S.**	**L-Cysteine Hydrochloride Injection manufactured by Sandoz Canada**
Description Clinical Pharmacology Indications and Usage Contraindications Warnings Precautions Adverse Reactions Dosage and Administration	No difference	
How Supplied	Single Dose Vial (10 x 10 mL) Pharmacy Bulk Package (5 x 50 mL)	Single Dose Vial (10 x 10 mL)
NDC	10 mL – 66758-004-01 10 x 10 mL – 66758-004-02 50 mL – 66758-005-01 5 x 50 mL – 66758-005-02	10 mL – 0781-8940-70 10 x 10 mL – 0781-8940-95
Manufacturing Statement	Manufactured for: SANDOZ	Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc.

Refer to the U.S. package insert for full prescribing information. It is important to note that there is a difference in the formatting of the labeling between the U.S. marketed L-Cysteine Hydrochloride Injection and the Sandoz Canada's L-Cysteine Hydrochloride Injection.

The bar code on the labeling of L-Cysteine Hydrochloride Injection manufactured by Sandoz Canada should be appropriately recognized by scanning systems used in the United States.

The Sandoz Canada's L-Cysteine Hydrochloride Injection is manufactured in compliance with good manufacturing practices in Quebec, Canada at an FDA inspected facility.

At this time, during the critical shortage of L-Cysteine Hydrochloride Injection, permissible importation of Sandoz Canada's L-Cysteine Hydrochloride Injection is limited to Sandoz. Importation or distribution of this product in the United States by any other entity will not be permitted. FDA has not approved Sandoz Canada's L-Cysteine Hydrochloride Injection, or any other L-Cysteine Hydrochloride Injection for marketing in the United States.

ORDERING PRODUCT: Customers can call Sandoz Inc.'s Customer Service telephone number (1.800.525.8747) Monday through Friday, from 8:00 am - 5:30 p.m. Eastern Standard Time, to find out how to order.

To report adverse events or quality problems with Sandoz Canada's L-Cysteine Hydrochloride Injection, please contact Sandoz Inc. at 1.800.525.8747 (Monday to Friday 8:00 am- 5:30 pm EST). Adverse events that may be related to the use of this product may also be reported to FDA's MedWatch Adverse Event Reporting Program either online, by telephone, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Telephone: 1.800.FDA.1088
- Regular mail: Use postage paid FDA form 3500 available at : www.fda.gov/medwatch/getforms.htm
  Mail to MedWatch FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Sincerely,

SANDOZ INC

Anthony Maffia III,
Vice President, Regulatory Affairs

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