Sun Pharma Global FZE
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URGENT – Doxil® (Doxorubicin Hydrochloride Liposome Injection) Shortage Update

January 27, 2012

Dear Healthcare Professional,

Due to the current critical shortage of Doxil® (doxorubicin HCL liposome injection) [Janssen Products, LP: 2 mg/mL-20 mg/10 mL and 50 mg/25 mL] in the United States (US) market, Sun Pharma Global FZE (Sun Pharma) through Caraco Pharmaceutical Laboratories Ltd is coordinating with the Food and Drug Administration (FDA) to provide an alternative treatment option during this critical shortage period.

On behalf of Sun Pharma, Caraco Pharmaceutical Laboratories Ltd has initiated temporary importation of Lipodox™ (Doxorubicin Hydrochloride Liposome Injection) into the US market. Sun Pharma's Lipodox™ Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) single use vials and Lipodox 50™ (Doxorubicin Hydrochloride Liposome Injection) 50 mg/25 mL (2 mg/mL) single use vials contain the same active ingredient, doxorubicin hydrochloride, in the same concentration as Doxil® (doxorubicin HCL liposome injection) [Janssen Products, LP: 2 mg/mL-20 mg/10 mL and 50 mg/25 mL] marketed in the United States.

Sun Pharma's Lipodox™ (Doxorubicin Hydrochloride Liposome Injection) 20 mg/10 mL (2 mg/mL) single use vials and Lipodox 50™ (Doxorubicin Hydrochloride Liposome Injection) 50 mg/25 mL (2 mg/mL) single use vials are manufactured in India at an FDA inspected facility, Sun Pharmaceutical Industries Limited – Halol, Gujarat.

Effective immediately, Sun Pharma will offer the following dosage forms:

Doxorubicin Hydrochloride Liposome Injection
20 mg/10 mL (2 mg/mL) - 10 mL single use vials (Lipodox™)
50 mg/25 mL (2 mg/mL) - 25 mL single use vials (Lipodox 50™)

In the US, the labeling for Doxil® (Doxorubicin Hydrochloride Liposome Injection) includes the following indications: i) treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy; ii) treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy; iii) treatment of multiple myeloma in combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy.

Refer to Sun Pharma's package insert for full prescribing information. Please note the important dosage and administration warning presented in Sun Pharma's product labeling.

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Sun Pharma's Lipodox™ and Lipodox 50™ (Doxorubicin Hydrochloride Liposome Injection) should be handled exactly as you have handled the FDA approved Doxil® (doxorubicin HCL liposome injection). Refrigerate unopened vials of doxorubicin hydrochloride liposome injection at 2° to 8°C (36° to 46°F). Avoid freezing. Prolonged freezing may adversely affect liposomal drug products; however, short-term freezing (less than 1 month) does not appear to have a deleterious effect on doxorubicin hydrochloride liposome injection.

To order Sun Pharma's Lipodox™ (Doxorubicin Hydrochloride Liposome Injection) 20 mg/10 mL (2 mg/mL) single use vials and Lipodox 50™ (Doxorubicin Hydrochloride Liposome Injection) 50 mg/25 mL (2 mg/mL) single use vials, please contact the shortage response team by phone 1888 835 2237 or fax 1800 980 2237.

To report adverse events or medication errors among patients administered Sun Pharma's Lipodox™ or Lipodox 50™ (Doxorubicin Hydrochloride Liposome Injection), please contact our partner Caraco Pharmaceutical Laboratories Limited at 1-800-818-4555.

Adverse events may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- 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

At this time, FDA's regulatory discretion for the importation and distribution of Sun Pharma's Lipodox™ (Doxorubicin Hydrochloride Liposome Injection) is limited to Sun Pharma Global FZE and its authorized distributor, Caraco Pharmaceutical Laboratories Ltd, during the critical shortage of Doxil. Importation or distribution of this product in the United States by any other entity is outside the scope of FDA's regulatory discretion, and FDA has not approved Sun Pharma's Lipodox™ product for marketing in the U.S.

Sincerely,

Vishwanath Kenkare
Manager
Sun Pharma Global FZE