CAELYX® (Pegylated Liposomal Doxorubicin Hydrochloride for Injection)

The major source of Caelyx® is Ben Venue Laboratories (BVL) in the United States. Quality assurance problems in the sterilization process were identified on inspection in November 2011 resulting in intermittent shortages of the drug anticipated to last until 2013.

The Canadian supplier, Janssen Inc. is periodically releasing batches of Caelyx®. All batches released to the market comply with regulators specifications and procedures. Until full production of Caelyx is resumed, Janssen Inc. recommends that:

- Existing CAELYX® stock only be used to continue treatments that have already been initiated.
- No new patients be initiated on CAELYX® treatment, until further notice.

Official indications:

- Monotherapy for metastatic breast cancer if increased cardiac risk associated with conventional doxorubicin.
- Advanced ovarian carcinoma if failed standard first-line therapy fails. Platinum-and paclitaxel-based chemotherapy is the current standard first-line treatment regimen.
- AIDS-related Kaposi’s sarcoma (KS) in patients with low CD4 counts (<200 CD4 lymphocytes/mm³) and extensive mucocutaneous or visceral disease if disease has progressed despite therapy or if intolerant to prior systemic combination chemotherapy comprising of at least two of the following agents: a vinca alkaloid, bleomycin and doxorubicin (or another anthracycline).

Treatment alternatives:

- Treatment decisions should be made on an individual patient basis after thorough discussion of the options between the patient and attending physician.
- Non-liposomal and non-pegylated forms of doxorubicin are not bioequivalent to CAELYX®. Therefore, these alternatives should only be used where the benefit outweighs the risks for individual patients.
- Non-anthracycline anticancer medicines may be considered.

In the US, FDA is allowing temporarily importation of an alternative brand of pegylated liposomal doxorubicin, Lipodox, manufactured by Sun Pharma Global FZE in India. Caraco currently does not ship drugs to Canada.
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References:


6. Personal communication Caraco Pharmaceuticals Customer Services & Sales 1-800-818-4555.