

## 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<sup>1</sup> resulting in intermittent shortages of the drug anticipated to last until 2013<sup>2</sup>.

The Canadian supplier, Janssen Inc. is periodically releasing batches of Caelyx®. All batches released to the market comply with regulators specifications and procedures.<sup>1</sup> 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.<sup>1</sup>
- No new patients be initiated on CAELYX® treatment, until further notice.<sup>1</sup>

### Official indications<sup>3</sup>:

- 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/mm<sup>3</sup>) 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.<sup>1</sup>
- 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.<sup>1</sup>
- Non-anthracycline anticancer medicines may be considered.<sup>4</sup>

*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.<sup>5</sup> Caraco currently does not ship drugs to Canada.<sup>6</sup>*

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References:

1. Janssen Inc. Dear Doctor Letter: Supply and Safety Update on CAELYX®\* (pegylated liposomal doxorubicin) 20 mg and 50 mg vials for injection. Available at [www.janssen.ca](http://www.janssen.ca). Accessed July 2012.
2. Personal communication Janssen Inc Medical Information, July 2012 – Telephone 1-800-567-3331.
3. e-CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2012. Caelyx [product monograph]. Available from: <http://www.e-cps.ca>. Accessed July 2012.
4. European Medicines Agency. Shortage of Caelyx (doxorubicin hydrochloride). Available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Medicine\\_QA/2011/09/WC500111745.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2011/09/WC500111745.pdf). Accessed July 2012.
5. American Society of Health-System Pharmacists. Drug Shortages. Available at <http://www.ashp.org/drugshortages/current/bulletin.aspx?id=806>. Accessed July 2012.
6. Personal communication Caraco Pharmaceuticals Customer Services & Sales 1-800-818-4555.