LIPODOXTM is an anti-neoplastic agent, anthracycline

Pre-Authorization Criteria:

VCHCP will authorize LIPODOX for FDA indicated treatment of ovarian cancer (progressive or recurrent), multiple myeloma (after failure of at least 1 prior therapy), and AIDS-related Kaposi’s sarcoma (after failure of or intolerance to prior systemic therapy)

Use - Unlabeled

Treatment of metastatic breast cancer, Hodgkin’s lymphoma, cutaneous T-cell lymphomas (mycosis fungoides and Sézary syndrome), advanced soft tissue sarcomas; advanced or metastatic uterine sarcoma

VCHCP requires that LOPODOX be prescribed by an Oncologist.

Dosage Forms: U.S.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. Injection, solution, as hydrochloride: Doxil®: 2 mg/mL (10 mL, 25 mL) [contains soy, sucrose]

Administration

Administer IVPB over 60 minutes; manufacturer recommends administering at initial rate of 1 mg/minute to minimize risk of infusion reactions until the absence of a reaction has been established, then increase the infusion rate for completion over 1 hour. Do NOT administer undiluted, as a bolus injection, or I.M. or SubQ.
Dosing: Adult

Details concerning dosing in combination regimens should also be consulted. **Liposomal formulations of doxorubicin should NOT be substituted for conventional doxorubicin hydrochloride on a mg-per-mg basis.**

**AIDS-related Kaposi’s sarcoma:** I.V.: 20 mg/m² every 3 weeks

**Multiple myeloma:** I.V.: 30 mg/m² on day 4 every 3 weeks (in combination with bortezomib) or

**Unlabeled dosing:** I.V.: 40 mg/m² every 4 weeks (in combination with vincristine and dexamethasone) (Rifkin, 2006)

**Ovarian cancer:** I.V.: 50 mg/m² every 4 weeks (minimum of 4 cycles is recommended)

**Breast cancer (unlabeled use):** I.V.: 50 mg/m² every 4 weeks (Keller, 2004)

**Uterine sarcoma (unlabeled use):** I.V.: 50 mg/m² every 4 weeks (Sutton, 2005)

**Warnings/Precautions**

**Boxed warnings:**

- Bone marrow suppression: See “Concerns related to adverse effects” below.

- Hepatic impairment: See “Disease-related concerns” below.

- Infusion reactions: See “Concerns related to adverse effects” below.

- Liposomal vs. conventional doxorubicin dosing: “Dosage form specific issues” below.

- Myocardial toxicity: See “Concerns related to adverse effects” below.

**REFERENCES**


©2013 UpToDate® - www.uptodate.com
Revision History:

Date Reviewed/No Updates: 1/16/13 by A. Reeves MD
Date Approved by P&T Committee: 7/24/12; 1/29/13
Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
Date Approved by P&T Committee: 1/28/14
Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Content Revised (Yes/No)</th>
<th>Contributors</th>
<th>Review/Revision Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/17</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
<tr>
<td>1/23/18</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
</tbody>
</table>