LIPODOX™ (doxorubicin hydrochloride liposime injection)

Effective Date: 07.24.12
Date Developed: 07.3.12 by Albert Reeves MD
Last Approval Date: 01.26.16, 01.24.17

LIPODOX™ 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: 01.16.13 by A. Reeves MD
Date Approved by P&T Committee: 07.24.12; 01.29.13
Date Reviewed/No Updates: 01.28.14 by C. Sanders MD
Date Approved by P&T Committee: 01.28.14
Date Reviewed/No Updates: 01.13.15 by C. Sanders, MD
Date Approved by P&T Committee: 01.27.15
Date Reviewed/No Updates: 01.26.16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.26.16
Date Reviewed/No Updates: 01.24.17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.24.17

<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>
</tbody>
</table>