Doxorubicin Hydrochloride Liposome Injection for intravenous infusion

WARNING: IMPAIRMENT OF HEARING AND VISION
Doxorubicin hydrochloride liposome injection should be administered only by or under the direct supervision of a health care provider with expertise in the treatment of patients with advanced cancer. A health care provider with expertise in the treatment of patients with advanced cancer is defined as a physician or a professional nurse who has received specific training in the intravenous administration of doxorubicin hydrochloride and who has an understanding of the serious adverse effects of doxorubicin hydrochloride. The health care provider or professional nurse must have had a minimum of 3 years of experience in the treatment of patients with advanced cancer and must have administered at least 150 mgs of doxorubicin hydrochloride.

CONTRAINDICATIONS
- Doxorubicin hydrochloride liposome injection is contraindicated in patients with a history of the following: severe hypersensitivity reactions to doxorubicin hydrochloride or any component of the liposome formulation or any component of the injection, severe cardiac toxicity (including cardiomyopathy, cardiomegaly, or left ventricle ejection fraction [LVEF] < 30%), severe hepatic dysfunction, severe renal insufficiency (creatinine clearance [CrCl] < 25 mL/min), severe pulmonary insufficiency, severe hematologic toxicity (anemia and/or neutropenia), or severe neurologic toxicity (e.g., cranial neuropathy).

WARNINGS AND PRECAUTIONS
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ADVERSE REACTIONS
- Hematologic: Anemia, neutropenia, thrombocytopenia, pancytopenia, leucopenia, granulocytopenia. Allergic/anaphylactoid-like infusion reactions have been reported. Medications/agents that have been reported to cause infusion-related reactions include aspirin, metoclopramide, doxorubicin, vincristine, or cyclophosphamide. However, the mechanism of these reactions is not known.

INFORMATION FOR PATIENTS
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The molecular formula of the drug is C H NO ·HCl; its molecular weight is 579.99. Spermatogenesis were observed in dogs after repeat doses of 1 mg/kg/day (about one half the

The corrected ratio may lie between 1 1 1

Nausea, vomiting, diarrhea, cough, and rhinitis were the most common adverse events. The incidence of bone marrow suppression was low; the incidence of alopecia was not statistically significant. The median duration of alopecia was 1.5 months (range: 0.5 to 15.6 months).

The plasma clearance of doxorubicin hydrochloride liposome injection was slow, with a mean duration of 24 to 35 L/h/m.

The pharmacokinetics of doxorubicin hydrochloride liposome injection have not been separately evaluated for patients 80 years of age or older. The pharmacokinetics of doxorubicin hydrochloride liposome injection have not been evaluated in patients with hepatic impairment.

Table 1: Pharmacokinetic Parameters of Doxorubicin Hydrochloride Liposome Injection in Patients With AIDS-Related Kaposi's Sarcoma

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± Standard Error</th>
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<tbody>
<tr>
<td>F (AUC ratio)</td>
<td>IV over 4 weeks</td>
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<td></td>
<td>95% CI for Hazard Ratio</td>
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|                           | Following its administration, doxorubicin hydrochloride liposome injection resulted in mild