

פברואר 2023

רופא/ה, רוקח/ת, נכבד/ה,

הנדון: Caelyx liposomal**מרכיבים פעילים:**

Doxorubicin hydrochloride 2.0 mg/ml

צורת מינון:

Liposome concentrate for solution for infusion

התוויות מאושרות:

First or second line therapy of aids related kaposi sarcoma in patients with low cd 4 counts and extensive mucocutaneous or visceral disease.

The treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel and platinum-based chemotherapy regimens and who may also be refractory to topotecan.

Refractory is defined as a patient having progressive disease while on treatment or within 6 months of completing treatment.

As monotherapy for patients with metastatic breast cancer where there is an increased cardiac risk.

In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.

חברת בקסטר אספקת שירותי בריאות בע"מ מבקשת להודיעכם על עדכונים בעלון לרופא של התכשיר בנדון.

העלון לרופא עודכן בתאריך ינואר 2023. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באמצעות קו תחת):

4.6 Fertility, pregnancy and lactation

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Women of childbearing potential/contraception in men and women

Due to the genotoxic potential of Doxorubicin hydrochloride (see section 5.3), women of childbearing potential should use effective contraceptive measures while being treated with Caelyx liposomal and for 8 months following completion of treatment.

Men are recommended to use effective contraceptive measures and to not father a child while receiving Caelyx liposomal and for 6 months following completion of treatment.

בברכה,

אנסטסיה דזיגר,ב,

מחלקת רישום ורגולציה,

בקסטר אספקת שירותי בריאות בע"מ.