

## Epi-Cell 50mg

חברת אמ.בי.איי פארמה בע"מ מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

### **התוויות התכשיר:**

For the treatment of a wide spectrum of neoplastic diseases including breast carcinoma, lung carcinoma (high doses), ovarian carcinoma, gastric carcinomas, soft tissue sarcoma.

Intravesical administration of epirubicin has been found to be beneficial in the treatment of superficial bladder carcinomas and in the prophylaxis of recurrences after transurethral resection.

IV administration for the treatment of advanced bladder carcinoma.

**מרכיב פעיל:** epirubicin hydrochloride 50mg  
**צורת המתן של התכשיר:** Solution for injection

### עדכונים בעלון לרופא, המהווה החמרה, נעשו בסעיפים הבאים:

#### **4.3 Contraindications**

If there is urinary backflow from the bladder to the renal pelvis (vesicorenal reflux) regular monitoring of the kidney function is necessary.

#### **4.4 Special warnings and precautions for use**

he risk of developing CHF or a cardiomyopathy increases rapidly with increasing total cumulative doses of epirubicin hydrochloride in excess of 900 mg/m<sup>2</sup>; this cumulative dose should only be exceeded with extreme caution.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The concurrent administration of epirubicin and other cardiotoxic drugs (e.g. 5-fluorouracil, cyclophosphamide, cisplatin, taxanes) or concomitant (or prior) radiotherapy of the mediastinum increase the cardiotoxicity of epirubicin.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

Women of child-bearing potential should be advised to avoid becoming pregnant during treatment and up to 6 months thereafter and should use effective contraceptive methods.

#### **4.8 Undesirable effects**

Gastrointestinal disorders-common: stomatitis, characterised by pain, burning sensation, erosions, ulcerations, bleeding;

##### *General disorders and administration site conditions*

Mucositis - may appear 5–10 days after the start of treatment, and usually involves stomatitis with areas of painful erosions, ulceration and bleeding, mainly along the side of the tongue and the sublingual mucosa.

ההחמרות מסומנות בצהוב. בעלון נעשו שינויים נוספים שאינם מהווים החמרה.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://data.health.gov.il/drugs/index.html#!/byDrug>  
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061, קדימה  
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