

ינואר 2026

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת סנדוז פרמצבטיקה ישראל בע"מ מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:

HYCAMTIN IV

Powder for solution for infusion

מרכיב פעיל: TOPOTECAN (AS HYDROCHLORIDE) 4mg/ml

ההתוויות המאושרות לתכשיר:

Topotecan monotherapy is indicated for the treatment of:

- patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy.
- patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.

Topotecan in combination with cisplatin is indicated for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease.

Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination.

אנא ראו מטה את העדכונים.

העלון לרופא נשלח לפרסום במאגר התרופות באתר משרד הבריאות:

<https://israeldrugs.health.gov.il/#!/byDrug>

כמו כן ניתן לקבלו מודפס על ידי פניה לחברת סנדוז פרמצבטיקה ישראל בע"מ.

לעדכונכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה

סנדוז פרמצבטיקה ישראל בע"מ

...

4.6 Fertility, pregnancy and lactation

...

Women of childbearing potential/Contraception in males and females

Topotecan has been shown to cause embryo-foetal lethality and malformations in preclinical studies (see section 5.3). As with other cytotoxic medicinal products, topotecan may cause foetal harm and therefore women of childbearing potential should be advised to avoid becoming pregnant during therapy with topotecan.

As with all cytotoxic chemotherapy, patients being treated with topotecan must be advised that they or their partner must use an effective method of contraception.

Women of childbearing potential should use effective contraceptive measures while being treated with topotecan and for 6 months following completion of treatment.

Men are recommended to use effective contraceptive measures and to not father a child while receiving topotecan and for 3 months following completion of treatment.

...