

ינואר 2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

## GEMCITABINE "EBEWE" 40 MG/ML

Concentrate for solution for infusion

מרכיב פעיל: gemcitabine (as hydrochloride) 40 mg/ml

### ההתוויות המאושרות לתכשיר:

Palliative treatment of patients with locally advanced or metastatic non-small cell lung cancer and locally advanced or metastatic adenocarcinoma of the pancreas and for patients with 5-FU refractory pancreatic cancer. Gemcitabine is indicated for the treatment of patients with bladder cancer at the invasive stage.

Breast cancer:

Gemcitabine in combination with paclitaxel is indicated for the treatment of patients with unresectable locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy.

Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

Ovarian cancer:

Gemcitabine in combination with carboplatin is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma whom have relapsed at least six months after platinum - based therapy.

אנא ראו מטה את העדכונים בצהוב.

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.

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**4.6 Fertility, pregnancy and lactation**

Women of childbearing potential / contraception in males and females

Due to the genotoxic potential of gemcitabine (see section 5.3), women of childbearing potential should use effective methods of contraception during treatment with gemcitabine and for 6 months after cessation of treatment.

Men should be advised to use effective methods of contraception and not to conceive a child during treatment with gemcitabine and for 3 months following its discontinuation.

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Fertility

In fertility studies gemcitabine caused hypospermatogenesis in male mice (see section 5.3). Therefore, men being treated with gemcitabine are advised not to father a child during and up to ~~3~~ 6-months after treatment and to seek further advice regarding cryoconservation of sperm prior to treatment because of the possibility of infertility due to therapy with gemcitabine.