SANDOZ

אפריל 2024

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 תוספות ההחמרה בכתב אדום.

בנוסף, בוצעו שינויי פורמט ותיקוני ניסוח קלים.

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,

Sandoz Pharmaceuticals Israel Ltd.
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סנדוז פרמצבטיקה ישראל בע"מ
ת.ד. 9015, תל אביב, 6109001, ישראל

מגר' דפנה סנדובסקי

רוקחת ממונה

סנדוז פרמצבטיקה ישראל בע"מ

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3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.

Clear, colourless to pale yellow solution.

pH: 2.0 – 2.8

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4.4 Special warnings and precautions for use

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Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with gemcitabine treatment. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, gemcitabine should be withdrawn immediately.

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Hepatic ~~or~~ and renal impairment
Gemcitabine should be used with caution in patients with hepatic or renal impairment as there is insufficient information from clinical studies to allow clear dose recommendation~~s~~ for ~~these~~ this patient population~~s~~ (see section 4.2).
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~~4~~**4.6Fertility, pregnancy and lactation**

Pregnancy
There are no adequate data from the use of gemcitabine in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). Based on results from animal studies and the mechanism of action of gemcitabine, this ~~medicinal product~~substance should not be used during pregnancy unless clearly necessary. Women should be advised not to become pregnant during treatment with gemcitabine and to warn their attending physician immediately, should this occur after all.

Breast-feeding
It is unknown whether gemcitabine is excreted in human milk, and adverse effects on the ~~breast-fed infant~~ suckling child cannot be excluded. ~~Gemcitabine "Ebewe" is contraindicated during breast-feeding~~ Breast-feeding must be discontinued during gemcitabine therapy. ~~(see section 4.3).~~
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4.8 Undesirable effects

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System Organ Class	Frequency grouping
Metabolism and nutrition disorders	Common Anorexia
Nervous system disorders	Common Headache, insomnia, somnolence Uncommon Clinical Cerebrovascular accident Very rare Posterior reversible encephalopathy syndrome (PRES) (see section 4.4)
Cardiac disorders	Uncommon Arrhythmias, predominantly supraventricular in nature, heart failure Rare Myocardial infarct
Vascular disorders	Rare Hypotension, Clinical signs of peripheral vasculitis and gangrene, ~~hypotension~~ Very rare Capillary leak syndrome (see section 4.4)
Respiratory, thoracic and mediastinal disorders	Very common Dyspnoea - usually mild and passes rapidly without treatment Common Cough, rhinitis Uncommon Interstitial pneumonitis (see section 4.4), bronchospasm – usually mild and transient but may require parenteral treatment Rare Pulmonary oedema, adult respiratory distress syndrome (see section 4.4)

Gastrointestinal disorders	Very common Vomiting, nausea Common Diarrhoea, stomatitis and ulceration of the mouth, constipation Very rare Ischaemic colitis
Hepatobiliary disorders	Very common Elevation of liver transaminases (AST and ALT) and alkaline phosphatase Common Increased bilirubin Uncommon Serious hepatotoxicity, including liver failure and death Rare Increased gamma-glutamyl transferase (GGT)
Skin and subcutaneous tissue disorders	Very common Allergic skin rash frequently associated with pruritus, alopecia Common Itching, sweating Rare Severe skin reactions, including desquamation and bullous skin eruptions, ulceration, vesicle and sore formation, scaling Very rare Toxic epidermal necrolysis, Stevens-Johnson syndrome Not known Pseudocellulitis, Acute generalized exanthematous pustulosis

Musculoskeletal and connective tissue disorders	Common Back pain, myalgia

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6.6 Special precautions for disposal and other handling

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Gemcitabine “Ebewe” 40mg/ml concentrate for solution for infusion must be diluted before use (see section 4.2 and 4.4). It is recommended to use large veins for the infusion to prevent damage to ~~blood vessels~~the vessel and extravasation.

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7. ~~NAME AND ADDRESS OF THE REGISTRATION HOLDER AND IMPORTER~~ LICENSE HOLDER AND IMPORTER'S NAME AND ADDRESS

Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel~~Novartis Israel Ltd., P.O.Box 7126, Tel Aviv, Israel~~