05/2024

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לצרכן של התכשיר

גמסיטאבין טבע תמיסה מרוכזת

Gemcitabine Teva Concentrate

Contains:

Gemcitabine(as Hydrochloride) 40 mg/ml

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Non-Small Cell Lung Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the palliative treatment of patients with locally advanced or metastatic non-small cell lung cancer.
Breast cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion 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.
Pancreatic Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas and for patients with 5-FU refractory pancreatic cancer.
Bladder Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the treatment of patients with bladder cancer at the invasive stage.
Ovarian cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma who have relapsed at least 6 months after platinum-based therapy.

ברצוננו להודיע שהעלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.4 Special warnings and precautions for use

[...]

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 If signs and symptoms suggestive of these reactions appear, gemcitabine should be withdrawn immediately.

[...]

Hepatic ~~or~~ and renal impairment

[...]

4.6 Fertility, pregnancy and lactation

Pregnancy

[...]

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.

[...]

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 Teva is contraindicated during breast-feeding (see section 4.3)~~Breast-feeding must be discontinued during Gemcitabine therapy.

[...]

4.8 Undesirable effects

[...]

System Organ Class	Frequency grouping
Nervous system disorders	*Common* Headache, Insomnia, Somnolence *Uncommon* Clinical Cerebrovascular accident *Very rare* Posterior reversible encephalopathy syndrome (PRES) (see section 4.4)
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

העלונים נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
https://israeldrugs.health.gov.il, וניתן לקבלו מודפס ע"י פניה לחברת טבע.