תאריך יולי 2021

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

גמסיטאבין טבע תמיסה מרוכזת, תמיסה מרוכזת להזרקה

Gemcitabine Teva concentrate, concentration for solution for infusion

Contains: 40 mg/ml, *gemcitabine (as hydrochloride)*

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

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

[...]

Hepatic or renal impairment

[...]

~~Patients with AST elevation tolerated gemcitabine without increasing toxicity, but patients with elevated bilirubin levels (>1.6 mg/dl) had a significantly increased risk of hepatotoxicity after gemcitabine therapy. A recommendation for dose reduction in the setting of liver dysfunction is promoted.~~

~~Patients with renal dysfunction presented with unusual side effects in response to gemcitabine, especially skin toxicity in the form of diffuse erythema and desquamation (see section Undesirable Effects)~~

[...]

4.8 Undesirable effects

[...]

System Organ Class	Frequency grouping
[...]	[...]
Blood and lymphatic system disorders	[...] *Very rare* Thrombocytosis, thrombotic microangiopathy
[...]	[...]
Skin and subcutaneous tissue disorders	[...] *Very rare* Toxic epidermal necrolysis Stevens-Johnson syndrome Not known Pseudocellulitis
Renal and urinary disorders	*Very common* ~~Increased creatinine~~

[...]

~~Combination use in non-small-cell lung cancer~~

~~***Grade 3 and 4 adverse events***~~
~~***gemcitabine plus cisplatin vs. paclitaxel plus cisplatin***~~

	~~% of Patients~~			
	~~Gemcitabine plus Cisplatin arm (N=293)~~		~~Paclitaxel plus Cisplatin arm (N=300)~~	
	~~Grade 3~~	~~Grade 4~~	~~Grade 3~~	~~Grade 4~~
~~**Hematologic Toxicity**~~				
~~Neutrophil count~~	~~24~~	~~39~~	~~18~~	~~57~~
~~Platelet count~~	~~22~~	~~28~~	~~4~~	~~2~~
~~Anemia~~	~~27~~	~~1~~	~~12~~	~~1~~
~~Infection~~	~~2~~	~~1~~	~~4~~	~~2~~
~~Febrile neutropenia~~	~~1~~	~~3~~	~~2~~	~~14~~
~~**Non-hematologic Toxicity**~~				
~~Cardiac toxicity~~	~~3~~	~~1~~	~~0~~	~~1~~
~~Renal toxicity~~	~~2~~	~~1~~	~~0~~	~~0~~
~~Nausea~~	~~37~~	~~0~~	~~25~~	~~0~~
~~Vomiting~~	~~7~~	~~28~~	~~3~~	~~21~~
~~Diarrhea~~	~~2~~	~~1~~	~~1~~	~~6~~
~~Hypersensitivity~~	~~0~~	~~0~~	~~2~~	~~1~~
~~Weakness~~	~~17~~	~~0~~	~~13~~	~~1~~
~~Neuropathy~~	~~9~~	~~0~~	~~5~~	~~0~~
~~All toxic effects highest Grade~~	~~21~~	~~68~~ ~~4 Grade 5~~	~~19~~	~~68~~ ~~5 Grade 5~~

[...]

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

ניתן לקבלו מודפס ע"י פניה לחברת טבע. ,http://www.health.gov.il