אוגוסט 2019

רופא/ה, רוקח/ת נכבד/ה,

הנדון: <u>Gemcitabine medac 200 mg - גמציטבין מדאק 200 מ"ג</u>
<u>Gemcitabine medac 1000 mg - גמציטבין מדאק 1000 מ"ג</u>
<u>Gemcitabine medac 1500 mg - גמציטבין מדאק 1500 מ"ג</u>

<u>מרכיב פעיל</u>:

Gemcitabine medac 200 mg: 200mg Gemcitabine
Gemcitabine medac 100 mg: 1000 mg Gemcitabine
Gemcitabine medac 150 mg: 1500 mg Gemcitabine

<u>צורת מינון</u>:

Powder For Solution For Infusion

<u>התוויות מאושרות</u>:
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.

חברת צמל ביו-פארמה בע"מ מבקשת להודיעכם על העדכונים הבאים בעלון לרופא של התכשיר.

החמרה מסומנת באמצעות <u>קו תחתי</u>, שמשמעותו היא תוספת מידע הקשור להחמרה.

4.2 Posology and method of administration

Recommended posology:
Cisplatin has been used at doses between 75-100 mg/ m^2 once every 3 <u>~~or 4~~</u> weeks

Paediatric population (<18 years)
Gemcitabine <u>is not recommended for use in children under 18 years of age</u> due to insufficient data on safety and efficacy.

Posterior reversible encephalopathy syndrome
Reports of posterior reversible encephalopathy syndrome (PRES) with potentially severe consequences have been reported in patients receiving gemcitabine as single agent or in combination with other chemotherapeutic agents. Acute hypertension and seizure activity were reported in most gemcitabine patients experiencing PRES, but other symptoms such as headache, lethargy, confusion and blindness could also be present. Diagnosis is optimally confirmed by magnetic resonance imaging (MRI). PRES was typically reversible with appropriate supportive measures. Gemcitabine should be permanently discontinued and supportive measures implemented, including blood pressure control and anti-seizure therapy, if PRES develops during therapy

Renal
Haemolytic uraemic syndrome
Clinical findings consistent with the haemolytic uraemic syndrome (HUS) were rarely reported (post- marketing data) in patients receiving gemcitabine (see section 4.8). HUS is a potentially life threatening disorder. Gemcitabine should be discontinued at the first signs of any evidence of microangiopathic haemolytic anaemia, such as rapidly falling haemoglobin with concomitant thrombocytopenia, elevation of serum bilirubin, serum creatinine, blood urea nitrogen, or LDH. Renal failure may not be reversible with discontinuation of therapy and dialysis may be required.

בברכה,

צמל ביו-פארמה בע"מ