

ספטמבר 2018

רופא/ה, רוקח/ת נכבד/ה,
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשירים:

Pemetrexed Teva® 100 mg
Pemetrexed Teva® 500 mg
Pemetrexed Teva® 1000 mg

Powder for Concentrate for Solution for Infusion

פמטרקסד טבע® 100 מ"ג

פמטרקסד טבע® 500 מ"ג

פמטרקסד טבע® 1000 מ"ג

אבקה להכנת תמיסה מרוכזת להכנת תמיסה למתן בעירווי

Pemetrexed Teva® 100 mg: each vial contains 100 mg Pemetrexed

Pemetrexed Teva® 500 mg: each vial contains 500 mg Pemetrexed

Pemetrexed Teva® 1000 mg: each vial contains 1000 mg Pemetrexed

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Malignant pleural mesothelioma:

Pemetrexed Teva in combination with cisplatin is indicated for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curatable surgery.

Non-small cell lung cancer:

Pemetrexed Teva in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

Pemetrexed Teva is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.

Pemetrexed Teva is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

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

Serious renal events, including acute renal failure, have been reported with pemetrexed alone or in association with other chemotherapeutic agents. Many of the patients in whom these

occurred had underlying risk factors for the development of renal events including dehydration or pre-existing hypertension or diabetes. Nephrogenic diabetes insipidus and renal tubular necrosis were also reported in post marketing setting with pemetrexed alone or with other chemotherapeutic agents. Most of these events resolved after pemetrexed withdrawal. Patients should be regularly monitored for acute tubular necrosis, decreased renal function and signs and symptoms of nephrogenic diabetes insipidus (e.g. hypernatraemia).

[...]

4.8 Undesirable effects

Uncommon cases of acute renal failure have been reported with pemetrexed alone or in association with other chemotherapeutic agents (see section 4.4). Nephrogenic diabetes insipidus and renal tubular necrosis have been reported in post marketing setting with an unknown frequency.

[...]

Erythematous oedema mainly of the lower limbs has been reported with an unknown frequency.

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
<http://www.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.