

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

Pemetrexed Teva 100 mg, 500mg, 100mg Powder for Concentrate for Solution for Infusion

פמטרקסד טבע 100 מ"ג, 500 מ"ג, 1000 מ"ג אבקה להכנת תמיסה מרוכזת להכנת תמיסה למתן בעירוי

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 curatible 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):

4.8 Undesirable effects

During post-marketing surveillance, the following adverse reactions have been reported in patients treated with pemetrexed:

Hyperpigmentation has been commonly reported. [...]

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

Infectious and non-infectious disorders of the dermis, the hypodermis and/or the subcutaneous tissue have been reported with an unknown frequency (e.g. acute bacterial dermohypodermitis, pseudocellulitis, dermatitis).
[...]

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