יוני 2018

רופא/ה נכבד/ה

רוקח/ת נכבד/ה

חברת לילי מבקשת להודיעכם כי העלון של התכשירים Alimta 100mg, Alimta 500mg עודכן.

בהודעה זו מצוינים רק הסעיפים בהם נעשה שינוי המהווה החמרה. קיימים עדכונים נוספים.

העלון המעודכן לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:

אלי לילי ישראל בע"מ, השיזף 4, רעננה , טל': 09-9606234

בברכה,

ד"ר שכון אבנר
רוקחת ממונה

Alimta 100 mg, Alimta 500 mg

אלימטה 100 מ"ג, אלימטה 500 מ"ג

Each vial contains 100 mg of pemetrexed (as pemetrexed disodium).

Each vial contains 500 mg of pemetrexed (as pemetrexed disodium).

ההתוויה המאושרת לתכשיר:

Malignant pleural mesothelioma:

ALIMTA 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:

ALIMTA 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 (see section 5.1).

ALIMTA 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 (see section 5.1).

ALIMTA 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 (see section 5.1).

Eli Lilly Israel Ltd. 4 HaSheizaf St.
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העדכונים העיקריים בעלון לרופא הינם:

4.4 Special warnings and precautions for use

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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.

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