

הנדון: התכשיר - PEMETREXED S.K. 500 mg

Powder for Concentrate for Solution for Infusion

ברצוננו להודיע על עדכון בעלון לרופא של התכשיר שבנדון. הודעה זו מתייחסת רק לסעיפים בהם נעשה שינוי המהווה החמרה. קיימים עדכונים מינוריים נוספים.

ההתוויה המאושרת:

Malignant pleural mesothelioma

PEMETREXED S.K. 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 curative surgery.

Non-small cell lung cancer

PEMETREXED S.K. 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).

PEMETREXED S.K. 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).

PEMETREXED S.K. 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).

העדכון המהותי שנעשה בעלון לרופא הנו:

4.4 Special warnings and precautions for use

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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).
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4.8 Undesirable effects:

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Nephrogenic diabetes insipidus and renal tubular necrosis have been reported in post marketing setting with an unknown frequency.
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העלון לרופא מפורסם במלואו באתר האינטרנט של משרד הבריאות, להלן הקישור:
<https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h>

ניתן לקבל את העלון המודפס במלואו באמצעות פניה לבעלת הרישום קיי.אס. קים אינטרנשיונל בע"מ, רח' ז'בוטינסקי 7, רמת גן,
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