SANDOZ A Novartis Division

רופא/ה, רוקח/ת נכבד/ה,

הנדון: הודעה על עדכון עלון לרופא

Pemetrexed Sandoz® 100mg, 500mg, 1000mg

Powder for concentrate for solution for infusion

אנו מבקשים להודיעך כי העלון לרופא של התכשירים שבנדון עודכן ביולי 2018.

Pemetrexed Sandoz® מתווה לאינדיקציות הבאות:

Malignant pleural mesothelioma

Pemetrexed Sandoz 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 Sandoz 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 Sandoz 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 Sandoz 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.

מרכיב פעיל: pemetrexed disodium

בעמודים הבאים מצויינים סעיפים בהם נעשה שינוי אשר מהווה החמרה או שינוי משמעותי.

למידע נוסף, יש לעיין בעלון לרופא המצורף כפי שאושר על ידי משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

http://www.old.health.gov.il/units/pharmacy/trufot/index.asp

ניתן לקבלו מודפס על ידי פניה לחברת נוברטיס ישראל בע"מ, רח' שחם 36, פתח תקוה, 03-920-1111.

בברכה,

ד"ר קרין שוורץ
רוקחת ממונה
נוברטיס ישראל בע"מ

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להלן פירוט השינויים העיקריים (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט אדום עם קו חוצה:)

4.4 Special warnings and precautions for use

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An insufficient number of patients has been studied with creatinine clearance of below 45 ml/min. Therefore, the use of pemetrexed in patients with creatinine clearance of < 45ml/min is not recommended (see section 4.2).

Patients with mild to moderate renal insufficiency (creatinine clearance from 45 to 79 ml/min) should avoid taking non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, and acetylsalicylic acid (> 1.3 g daily) for 2 days before, on the day of, and 2 days following pemetrexed administration (see section 4.5).
In patients with mild to moderate renal insufficiency eligible for pemetrexed therapy, NSAIDs with long elimination half-lives should be interrupted for at least 5 days prior to, on the day of, and at least 2 days following pemetrexed administration (see section 4.5).

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).

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4.8 Undesirable effects

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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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