SANDOZ

אפריל 2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת סנדוז פרמצבטיקה ישראל בע"מ מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:

METHOTREXAT "EBEWE" 100 MG/ML

Concentrate for solution for infusion

מרכיב פעיל: methotrexate 100mg/ml

ההתוויות המאושרות לתכשיר:

Antineoplastic Chemotherapy: Treatment of gestational choriocarcinoma, chorioadenoma destruens and hydatidiform mole. Palliation of acute lymphocytic leukemia. In the treatment and prophylaxis of meningeal leukemia. Greatest effect has been observed in palliation of acute lymphoblastic (stem cell) leukemias in children. In combination with other anticancer agents, methotrexate may be used for the induction of remission,but is most commonly used in maintenance of induced remissions. Methotrexate may be used alone or in combination with other antineoplastics in the management of breast cancer, epidermoid cancers of the head and neck, lung cancer (particularly squamous cell and small cell types), bladder cancer and osteogenic cancer.
Methotrexate is effective in the treatment of the advanced stages (III and IV, Peters' Staging System) of lymphosarcoma, particularly in children, and in advanced cases of mycosis fungoides.

אנא ראו מטה את העדכונים.

העלון לרופא נשלח לפרסום במאגר התרופות באתר משרד הבריאות:

https://israeldrugs.health.gov.il/#!/byDrug

כמו כן ניתן לקבלו מודפס על ידי פניה לחברת סנדוז פרמצבטיקה ישראל בע"מ.

לעדכונכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה

סנדוז פרמצבטיקה ישראל בע"מ

Sandoz Pharmaceuticals Israel Ltd.
P.O.Box 9015, 6109001, Tel Aviv, Israel

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עדכון העלון לרופא:

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4.4. Special warnings and precautions for use

There are reports of leukoencephalopathy in patients who received oral methotrexate.

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Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking methotrexate (see section 4.8). Exposure to intense sunlight or UV rays should be avoided unless medically indicated. Patients should use adequate sun-protection to protect themselves from intense sunlight.

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4.5. Interaction with other medicinal products and other forms of interaction

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Concurrent administration of metamizole and methotrexate can increase the haematotoxic effect of methotrexate, especially in elderly patients. Therefore, coadministration should be avoided.

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4.8. Undesirable effects

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Nervous system disorders

Very common: headaches, vertigo ~~dizziness~~

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Gastrointestinal disorders*

Very common: Loss of appetite ~~anorexia,~~ diarrhoea (especially in the first 24–48 hours after using methotrexate), abdominal pains, nausea, vomiting, inflammation and ulceration of the mucosa in the mouth and the throat (especially in the first 24–48 hours after using methotrexate)

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Skin and subcutaneous tissue disorders*

Very common: alopecia

Common: exanthema, erythema, pruritus, ~~photosensitivity~~, skin ulcerations

Uncommon: severe toxic manifestations: herpetiform skin eruptions, Stevens-Johnson syndrome*, toxic epidermal necrolysis (Lyell's syndrome)*, urticaria, increased skin pigmentation, nodulosis, painful erosions of psoriatic plaques, impaired wound healing, photosensitivity reactions

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General disorders and administration site reactions

Very common: fatigue ~~exhaustion~~, malaise

Uncommon: pyrexia, ~~in intramuscular administration of methotrexate, local adverse reactions (burning sensation) or damage (sterile abscess formation, destruction of adipose tissue) may appear at the injection site.~~

Not known: ~~injection site necrosis,~~ chills, ~~oedema~~