תעשיות פרמצבטיות בע"מ

תאריך: נובמבר 2018

רופא/ה, רוקח/ת נכבד/ה

חברת טבע מודיעה שמשרד הבריאות אישר את העדכונים הבאים בעלון <u>לרופא</u> של התכשיר:

פקליטקסל טבע תמיסה מרוכזת להכנת תמיסה לעירוי

Paclitaxel Teva Concentrate for solution for infusion

Contains: Paclitaxel 6 mg/ml

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

Paclitaxel Teva is indicated, alone or in combination, for the treatment of advanced carcinoma of the ovary.

For the treatment of metastatic breast cancer after failure of combination chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

Paclitaxel Teva is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.

Advanced non-small cell lung cancer: Paclitaxel Teva , in combination with cisplatin, is indicated for the treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.

Kaposi's sarcoma: Paclitaxel Teva is indicated in the second-line treatment of AIDS-related Kaposi's sarcoma.

For the treatment of advanced gastric carcinoma.

ברצוננו להודיע שהעלון לצרכן עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (החמרות מסומנות בצהוב):

4.2 Dosage and Method of Administration

[…]
Elderly patients
- Studies demonstrating the safety and efficacy of paclitaxel in elderly patients (over 65 years of age) have not been performed. Paclitaxel is therefore not recommended for use in elderly patients.

4.3 Contraindications
[…]
The use of paclitaxel in pregnant women is contraindicated.

4.4 Special Warnings and Precautions for Use

[…]
Regular respiratory and cardiac examinations are particularly important in the first hour of administration.

Mild hypersensitivity reactions such as skin reactions, flush, mild dyspnoea, hypotension or tachycardia do not necessitate discontinuation of therapy.

Since with neutropenia and thrombocytopenia the risk of infection and bleeding is increased, dental treatment during paclitaxel therapy should only be carried out in exceptional cases. Patients must be advised of the importance of appropriate oral hygiene.

Peripheral neuropathy commonly occurs during treatment with paclitaxel, but severe symptoms rarely develop. In case of severe peripheral neuropathies a dose reduction by 20% in subsequent treatment courses is recommended. Prior treatment with other neurotoxic agents may result in a dose-limiting cumulative neurotoxicity.

The use of paclitaxel is relatively contraindicated in patients with hepatic dysfunction, herpes zoster, varicella zoster, serious infections or bone marrow depression, in patients who have previously undergone chemotherapy or radiotherapy, and in patients who either suffer from cardiac dysfunction or have had a prior cardiac infarction.

Since Paclitaxel Teva contains ethanol (396 mg/ml), attention must be paid to a potential impact on the central nervous system or other effects. Special care should be taken in patients with alcohol abuse disorders, patients with hepatic impairment, epileptic patients, and patients with cerebral impairment. Diphenhydramine (premedication) may intensify the effect of alcohol.

Concomitant or preceding therapy with cytotoxic agents or radiotherapy may increase the myelotoxicity of paclitaxel.

Since myelotoxicity may result in a changed immune reaction mechanism, immunisation with live virus vaccines should be avoided. Patients undergoing paclitaxel therapy should also avoid contact with persons who recently received oral polio vaccine.

4.5 Interactions with Other Medicinal Products

[…]

Concomitant or preceding therapy with cytotoxic agents or radiotherapy may increase the myelotoxicity of paclitaxel.

Since myelotoxicity may result in a changed immune reaction mechanism, immunisation with live virus vaccines should be avoided. Patients undergoing paclitaxel therapy should also avoid contact with persons who recently received oral polio vaccine.

4.6 Pregnancy and Lactation

[…]
The use of paclitaxel in pregnant women is contraindicated.

4.8 Undesirable Effects

[…]
Cardiac disorders
Uncommon: ECG changes of no or minor clinical relevance were reported, but were not safely associated with paclitaxel.

Hepato-biliary disorders
Very rare: […] peripheral oedema
[…]

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

http://www.health.gov.il, וניתן לקבלו מודפס ע"י פניה לחברת טבע.