

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

Oxaliplatin Teva

5 mg/ml, concentrate for solution for infusion

אוקסליפלטיין טבע, 5 מ"ג/מ"ל, תמיסה מרוכזת להכנת תמיסה לעירוי

Contains: Oxaliplatin 5 mg/ml

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Oxaliplatin in combination with 5- fluorouracil (5-FU) and folinic acid (FA) is indicated for :

- Adjuvant treatment of stage III (Duke's C) colon cancer after complete resection of the primary tumour.
- Treatment of metastatic colorectal cancer.

Oxaliplatin in combination with leucovorin, irinotecan and 5-fluorouracil is indicated for the firstline treatment of patients with metastatic pancreatic adenocarcinoma (based on NCCN guidelines, version 2.2014).

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.4 Special warnings and precautions for use

Nausea, vomiting, diarrhoea, dehydration and haematological changes

If haematological toxicity occurs (neutrophils $< 1.5 \times 10^9/l$ or platelets $< 50 \times 10^9/l$), administration of the next course of therapy should be postponed until haematological values return to acceptable levels. A full blood count with white cell differential should be performed prior to start of therapy and **before** each subsequent course. **Myelosuppressive effects may be additive to those of concomitant chemotherapy. Patient with severe and persistent myelosuppression are at high risk of infectious complications.**

[...]

QT prolongation

QT prolongation may lead to an increased risk for ventricular arrhythmias including Torsade de Pointes, which can be fatal (see section 4.8). **The QT interval should be closely monitored on a regular basis before and after administration of oxaliplatin.** Caution should be exercised in patients with a history or a predisposition for prolongation of QT, those who are taking medicinal products known to prolong QT interval, and those with electrolyte disturbances such as hypokalaemia, hypocalcaemia, or hypomagnesaemia. In case of QT prolongation, oxaliplatin treatment should be discontinued (see sections 4.5 and 4.8).

[...]

4.8 Undesirable effects

Injury, poisoning and procedural complications

Common- Fall

+ Very common: frequent allergy /allergic reactions, occurring mainly during perfusion, sometimes fatal allergic reactions such as skin rash, in particularly urticaria, conjunctivitis, rhinitis). Common anaphylactic reactions, including bronchospasm, angioedema, low blood pressure and anaphylactic shock. **Delayed hypersensitivity has also been reported with oxaliplatin hours or even days after the infusion.**

Post-marketing experience with frequency not known

aemolytic uremic syndrome, **autoimmune pancytopenia, pancytopenia, secondary leukaemia.**

Post-marketing experience with frequency not known

Convulsion, **ischemic and haemorrhagic cerebrovascular disorder.**

Cardiac disorders

Post-marketing experience with frequency not known

QT prolongation, which may lead to ventricular arrhythmias including Torsade de Pointes, which may be fatal (see section 4.4).

Acute coronary syndrome, including myocardial infarction and coronary arteriospasm and angina pectoris in patients treated with oxaliplatin in combination with 5-FU and bevacizumab.

Respiratory, thoracic and mediastinal disorders

Post-marketing experience with frequency not known

Laryngospasm. **Pneumonia and bronchopneumonia, including fatal outcomes.**

Post-marketing experience with frequency not known

Intestinal ischemia, including fatal outcomes (see section 4.4).Gastrointestinal ulcer and perforation, which can be fatal (see section 4.4). **Oesophagitis.**

Skin and subcutaneous tissue disorders

Post-marketing experience with frequency not known

Hypersensitivity vasculitis.

[...]

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
רח' התאנה 1, פארק תעשייה חמ"ן ת.ד. 975, שוהם 6085001 | טל: 972-3-6864000 | <https://israeldrugs.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.