

נובמבר 2020

רופאה, רוקח/ת נכבד/ה,

הנדון: עדכון עלון לרופא של התכשיר:
Oxaliplatin medac 50mg מ"ג 50 מדאק
Oxaliplatin medac 100mg מ"ג 100 מדאק
Oxaliplatin medac 150mg מ"ג 150 מדאק

מרכיב פעיל:

OxALIPLATIN 50mg/vial
OxALIPLATIN 100mg/vial
OxALIPLATIN 150mg/vial

Powder for solution for infusion

צורת מינון:

התוויה מאושרת:

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 primary tumor.
- 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).

חברת צמל ביו-פארמה בע"מ מבקשת להודיעכם על העדכונים הבאים בעלון לרופא של התכשיר.

בהודעה זו מצוינים השינויים המהווים החמרה בלבד. ההחמרות מודגשות בקו תחתון.

להלן ההחמרות:

4.4 Special warnings and precautions for use

Nausea, vomiting, diarrhoea, dehydration and haematological changes

.... 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. Sepsis, neutropenic sepsis and septic shock have been reported in patients treated with oxaliplatin including fatal outcomes (see section 4.8).

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....

4.8 Undesirable effects

Injury, poisoning and procedural complications

Common- Fall

+ Very common: frequent allergy/allergic reactions, occurring mainly during perfusion, sometimes fatal (frequent 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.

Postmarketing experience with frequency not known

Haemolytic uremic syndrome, autoimmune pancytopenia, pancytopenia, secondary leukaemia

Postmarketing experience with frequency not known

Convulsion, ischaemic 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

Postmarketing experience with frequency not known

Hypersensitivity vasculitis

6.6 Special precautions for disposal and other handling

Special precautions for administration

- DO NOT administer extravascularly.

Instruction for use with 5-fluorouracil

Any reconstituted solution that shows evidence of precipitation should not be used and should be destroyed with due regard to legal requirements for disposal of hazardous waste (see below).

העלון המאושר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו-פארמה בע"מ, טלפון: 073-7151111.

בברכה,

צמל ביו-פארמה בע"מ