אוגוסט 2023

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

אוקסליפלטין מדאק 50מ"ג **OXALIPLATIN MEDAC 50 MG**

אוקסליפלטין מדאק 100מ"ג **OXALIPLATIN MEDAC 100 MG**

מרכיב פעיל: Oxaliplatin

צורת מינון: POWDER FOR SOLUTION FOR INFUSION

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 tumour
• Treatment of metastatic colorectal cancer.
Oxaliplatin in combination with leucovorin, irinotecan and 5-fluorouracil is indicated for the first-line treatment of patients with metastatic pancreatic adenocarcinoma (based on NCCN guidelines, version 2.2014).

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

1. NAME OF THE MEDICINAL PRODUCT

OXALIPLATIN MEDAC 50 MG
OXALIPLATIN MEDAC 100 MG
~~OXALIPLATIN MEDAC 150 MG~~

4.4 Special warnings and precautions for use

[…]

Renal impairment

Patients with mild to moderate renal impairment should be closely monitored for adverse reactions and the dose adjusted according to toxicity (see section 5.2).

~~Due to limited information on safety in patients with moderately impaired renal function, administration should only be considered after suitable appraisal of the benefit/risk for the patient. In this situation, renal function should be closely monitored and dose adjusted according to toxicity.~~

4.6 Fertility, pregnancy and lactation

[…]

Contraception in males and females

Due to the genotoxic potential of oxaliplatin (see section 5.3), women of childbearing potential have to use effective contraception during and up to ~~4~~ 9 months after treatment. Men have to use effective contraception during and up to 6 months after treatment.

5.2 Pharmacokinetic properties

[…]

Renal impairment

The effect of renal impairment on the disposition of oxaliplatin was studied in patients with varying degrees of renal function. Oxaliplatin was administered at a dose of 85 mg/m² in the control group with a normal renal function (CLcr > 80 ml/min, N = 12) and in patients with mild (CLcr = 50 to 80 ml/min, N = 13) and moderate (CLcr = 30 to 49 ml/min, N = 11) renal impairment, and at a dose of 65 mg/m² in patients with severe renal impairment (CLcr < 30 ml/min, N = 5). Median exposure was 9, 4, 6 and 3 cycles, respectively, and PK data at cycle 1 were obtained in 11, 13, 10 and 4 patients respectively.

There was an increase in plasma ultrafiltrate (PUF) platinum AUC, AUC/dose and a decrease in total and renal CL and Vss with increasing renal impairment especially in the (small) group of patients with severe renal impairment: point estimate (90 % CI) of estimated mean ratios by renal status versus normal renal function for AUC/dose were 1.36 (1.08, 1.71), 2.34 (1.82, 3.01) and 4.81 (3.49, 6.64) for patients with mild and moderate and in severe renal failure respectively.

Elimination of oxaliplatin is significantly correlated with the creatinine clearance. Total PUF platinum CL was respectively 0.74 (0.59, 0.92), 0.43 (0.33, 0.55) and 0.21 (0.15, 0.29) and for Vss respectively 0.52 (0.41, 0.65), 0.73 (0.59, 0.91) and 0.27 (0.20, 0.36) for patients with mild, moderate and severe renal failure respectively. Total body clearance of PUF platinum was therefore reduced by respectively 26 % in mild, 57 % in moderate, and 79 % in severe renal impairment compared to patients with normal function.

Renal clearance of PUF platinum was reduced in patients with impaired renal function by 30 % in mild, 65 % in moderate, and 84 % in severe renal impairment compared to patients with normal function.

There was an increase in beta half-life of PUF platinum with increasing degree of renal impairment mainly in the severe group. Despite the small number of patients with severe renal dysfunction, these data are of concern in patients in severe renal failure and should be taken into account when prescribing oxaliplatin in patients with renal impairment (see sections 4.2, 4.3 and 4.4).

בהודעה זו כלולים העדכונים המהותיים בלבד. העלונים כוללים עדכונים נוספים.
תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת ~~בקו חוצה~~, החמרה מסומנת ברקע צהוב.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות באתר משרד הבריאות www.health.gov.il, וניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו-פארמה בע"מ, טלפון: 073-7151111.

בברכה,

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