תאריך: אוקטובר 2021

רופא/ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

אירינוטקן טבע 20 מ"ג למ"ל, תמיסה מרוכזת לעירוי תוך ורידי

Irinotecan Teva 20 mg/ml, concentrate for solution for infusion

Contains: 20 mg/ml, Irinotecan Hydrochloride Trihydrate

עדכונים בעלון לרופא

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

Irinotecan Teva is indicated for the treatment of patients with metastatic colorectal cancer:

- In combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for metastatic disease.
- As a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen.
- For the treatment of patients with small cell lung cancer.
- For the treatment of patients with gastric cancer.
- Irinotecan in combination with leucovorin, Oxaliplatin and 5-fluorouracil for the first-line treatment of patients with metastatic pancreatic adenocarcinoma.

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

4.4 Special warnings and precautions for use

[...]

Others

Concomitant administration of irinotecan with a strong inhibitor (e.g., ketoconazole) or inducer (e.g., rifampicin, carbamazepine, phenobarbital, phenytoin, apalutamide) of CYP3A4 may alter the metabolism of irinotecan and should be avoided (see section 4.5).

[...]

Contraception in women of childbearing potential / men:
Due to the potential for genotoxicity, advise female patients of reproductive potential to use highly effective contraception during treatment and for 6 months after the last dose of irinotecan.
Due to the potential for genotoxicity, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of irinotecan (see section 4.6).

Breast-feeding
Due to the potential for adverse reactions in nursing infants, breast-feeding should be discontinued for the duration of Irinotecan Teva therapy (see sections 4.3 and 4.6).

[...]

4.5 Interaction with other medicinal products and other forms of interaction
[...]
Strong CYP3A4 and/or UGT1A1 inducing medicinal products: (e.g. rifampicin, carbamazepine, phenobarbital, phenytoin or apalutamide):
[...]
Other combinations
[...]
Antineoplastic agents (including flucytosine as a prodrug for 5-fluorouracil): Adverse effects of irinotecan, such as myelosuppression, may be exacerbated by other antineoplastic agents having a similar adverse-effect profile.
[...]

4.6 Fertility, pregnancy and lactation
Contraception
Due to the potential for genotoxicity, advise female patients of reproductive potential to use highly effective contraception during treatment and for 6 months after the last dose of irinotecan (see section 4.4).
Due to the potential for genotoxicity, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of irinotecan (see section 4.4).

[...]
Pregnancy
[...]
Women of childbearing potential should not be started on irinotecan until pregnancy is excluded. Pregnancy should be avoided if either partner is receiving irinotecan

Breast-feeding
The available data are limited but suggested that irinotecan and its metabolite are excreted in human milk
[...]
Fertility
There are no human data on the effect of irinotecan on fertility. In animals adverse effects of irinotecan on the fertility of offspring have been documented (see section 5.3). **Prior to starting to take irinotecan consider advising patients on the preservation of gametes.**