

יולי 2021

רופא/ה, רוקח/ת נכבד/ה,  
ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר

## Campto

המרכיב הפעיל:

### **Irinotecan hydrochloride**

התוויה:

Campto 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..

להלן העדכונים העיקריים בעלון לרופא:

#### 4.4 Special warnings and precautions for use

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##### **Others**

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Contraception in wWomen of childbearing potential/ and men: **have to use effective contraception during and up to 1 month and 3 months after treatment, respectively.**  
**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 CAMPTO therapy (see sections 4.3 and 4.6).**

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**Babies and young children (below 2 years of age) may not yet be diagnosed with HFI. Medicines (containing fructose) given intravenously may have life-threatening effects in individuals with HFI and should not be administered in this population unless there is an overwhelming clinical need and no alternatives are available.**

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#### 4.5 Interaction with other medicinal products and other forms of interaction

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##### **Concomitant use not recommended (see section 4.4)**

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**Strong CYP3A4 and/or UGT1A1 inducing medicinal products:** (e.g., rifampicin, carbamazepine, phenobarbital, ~~or~~ phenytoin **or apalutamide**):

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##### **Other combinations**

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**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).

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##### Pregnancy

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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.

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##### Fertility

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**Prior to starting to take CAMPTO consider advising patients on the preservation of gametes.**

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים בעלון לרופא ולצרכן הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. בהודעה זו מצוינים רק העדכונים העיקריים. קיימים עדכונים נוספים. העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות: <https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h> לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייר פי אף אי פרמצבטיקה ישראל בע"מ שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,

עשת אושרית  
רוקחת ממונה