



מאי 2018

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא (עלון לצרכן במתכונת עלון לרופא) של התכשיר **Campto** המרכיב הפעיל:

Irinotecan hydrochloride 20mg/mL

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:

4.3. Contraindications

- Chronic inflammatory bowel disease and/or bowel obstruction (see section 4.4).
- History of severe ~~H~~hypersensitivity ~~reactions~~ to ~~the active substance(s)~~irinotecan hydrochloride trihydrate or to ~~any~~one of the excipients ~~listed in section 6.1 of CAMPTO~~.
- Lactation (see section 4.6 and section 4.4).
- Bilirubin > 3 times the upper limit of the normal range (see section 4.4).
- Severe bone marrow failure.
- WHO performance status > 2.
- Concomitant use with St. John's Wort (see section 4.5).
- Live attenuated vaccines (see section 4.5).

4.4 Special warnings and **special** precautions for use

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Immunosuppressant effects/increased susceptibility to infections

~~Administration of live or live-attenuated vaccines in patients immunocompromised by chemotherapeutic agents including irinotecan, may result in serious or fatal infections. Vaccination with a live vaccine should be avoided in patients receiving irinotecan. Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.~~

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

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Live attenuated vaccines: Risk of generalised reaction to vaccines, possibly fatal. Concomitant use is contraindicated during treatment with irinotecan and for 6 months following discontinuation of chemotherapy.

Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.

4.7. Effects on ability to drive and use machines

CAMPTO[®] has moderate influence on the ability to drive and use machines. Patients should be warned about the potential for dizziness or visual disturbances which may occur within 24 hours following the administration of CAMPTO[®], and advised not to drive or operate machinery if these symptoms occur.

4.8. Undesirable effects

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POST-MARKETING SURVEILLANCE

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Hepatobiliary disorders	<ul style="list-style-type: none">• Steatohepatitis• Hepatic steatosis
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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלונים המעודכים 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 פיזר פי אף אי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
אורטל עבודי
רוקחת ממונה