

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 06.07.2016

שם תכשיר באנגלית ומספר הרישום

CAMPTO 106.12.29047.00

שם בעל הרישום: פיזר פי אף אי פרמצבטיקה בע"מ

**טופס זה מיועד לפרוט החמרות בלבד !**

החמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Special warnings and precautions for use		
Therapeutic indications	<p>Campto is indicated for the treatment of patients with metastatic colorectal cancer:</p> <ul style="list-style-type: none"> <li>In combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for metastatic disease.</li> <li>As a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen.</li> <li>For the treatment of patients with small cell lung cancer.</li> <li>For the treatment of patients with gastric cancer.</li> </ul>	<p>Campto is indicated for the treatment of patients with metastatic colorectal cancer:</p> <p>In combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for metastatic disease.</p> <p>As a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen.</p> <p>For the treatment of patients with small cell lung cancer.</p> <p>For the treatment of patients with gastric cancer.</p> <ul style="list-style-type: none"> <li>Irinotecan in combination with leucovorin, Oxaliplatin and 5-fluorouracil for the first-line treatment of patients with metastatic pancreatic adenocarcinoma (based on NCCN guidelines, version 2.2015)</li> </ul>
Special precautions for storage		
Posology and method of administration		
Contraindications	<p>Campto is contraindicated in patients with a known hypersensitivity to the drug or its excipients. (See section <b>שגיאה! מקור ההפניה לא נמצא.</b> Special warnings and precautions for use, Hypersensitivity Reactions.)</p>	<ul style="list-style-type: none"> <li>Chronic inflammatory bowel disease and/or bowel obstruction (see section 4.4).</li> <li>History of severe hypersensitivity reactions to irinotecan hydrochloride trihydrate or to one of the excipients of CAMPTO.</li> <li>Lactation (see section 4.6 and section 4.4).</li> <li>Bilirubin &gt; 3 times the upper</li> </ul>

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).		
		<b>Undesirable effects</b>