

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 3102.50)

תאריך 09/07/2014

שם תכשיר באנגלית ומספר הרישום **Avastin [131-59-31060-00]**

שם בעל הרישום **רוש פרמצבטיקה (ישראל) בע"מ**

! טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות - עלון לרופא		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>[...]</p> <p>Some of the adverse reactions are reactions commonly seen with chemotherapy; Avastin may exacerbate these reactions when combined with chemotherapeutic agents. Examples include palmar-plantar erythrodysesthesia syndrome with <b>pegylated liposomal doxorubicin</b> or capecitabine, peripheral sensory neuropathy with paclitaxel or oxaliplatin, and <b>nail disorders or alopecia with paclitaxel</b></p> <p>[...]</p> <p><i>Fistulae</i> (see section 4.4)</p> <p>[...]</p> <p>In clinical trials, gastrointestinal fistulae have been reported with an incidence of up to 2% in patients with metastatic colorectal cancer and ovarian cancer, but were also reported less commonly in patients with other types of cancers. <b>In a study of platinum resistant ovarian cancer (study MO22224), an incidence of up to 2.2% of fistulae involving the urinary bladder and female genital tract (including rectovaginal fistulae) was observed.</b></p> <p>Uncommon (<math>\geq 0.1\%</math> to <math>&lt; 1\%</math>) reports of other types of fistulae that involve areas of the body other than the gastrointestinal tract (e.g. bronchopleural and biliary fistulae) were observed across various indications. Fistulae have also been reported in post-marketing experience.</p> <p>[...]</p>	<p>[...]</p> <p>Some of the adverse reactions are reactions commonly seen with chemotherapy, (e.g. palmar-plantar erythrodysesthesia syndrome with capecitabine and peripheral sensory neuropathy with paclitaxel or oxaliplatin); however, an exacerbation by Avastin therapy can not be excluded.</p> <p>[...]</p> <p><i>Fistulae</i> (see section 4.4)</p> <p>[...]</p> <p>In clinical trials, gastrointestinal fistulae have been reported with an incidence of up to 2% in patients with metastatic colorectal cancer and ovarian cancer, but were also reported less commonly in patients with other types of cancers. Uncommon (<math>\geq 0.1\%</math> to <math>&lt; 1\%</math>) reports of other types of fistulae that involve areas of the body other than the gastrointestinal tract (e.g. bronchopleural, urogenital and biliary fistulae) were observed across various indications. Fistulae have also been reported in post-marketing experience.</p> <p>[...]</p>	<p style="text-align: center;">Undesirable effects</p>

ההחמרות המבוקשות - עלון לרופא

טקסט חדש	טקסט נוכחי	פרק בעלון
<p><i>Elderly patients</i> [...] In one clinical trial, the incidence of hypertension of grade <math>\geq 3</math> was twofold higher in patients aged &gt; 65 years than in the younger age group (&lt;65 years). In a study of platinum-resistant recurrent ovarian cancer patients, alopecia, mucosal inflammation, peripheral sensory neuropathy, proteinuria and hypertension were also reported and occurred at a rate at least 5% higher in the CT + BV arm for bevacizumab treated patients <math>\geq 65</math> years of age compared with bevacizumab-treated patients aged &lt; 65 years.</p>	<p><i>Elderly patients</i> [...] In one clinical trial, the incidence of hypertension of grade <math>\geq 3</math> was twofold higher in patients aged &gt; 65 years than in the younger age group (&lt;65 years).</p>	

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 05/10/2014