

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 25/07/2017

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

שם בעל הרישום: Roche Pharmaceuticals (Israel) Ltd

! טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות - עלון לרופא		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>[...]</p> <p>Table 1: Adverse Reactions by Frequency</p> <p>Metabolism and nutrition disorders: Hypomagnesaemia and Hyponatraemia were added as a "Very Common" adverse reactions.</p> <p>Respiratory, thoracic and mediastinal disorders: Epistaxis and Cough were added as a "Very Common" adverse reactions.</p> <p>Musculoskeletal and connective tissue disorders: Myalgia was added as a "Very Common" adverse reaction.</p> <p>[...]</p> <p>Table 2: Severe Adverse Reactions by Frequency</p> <p>Metabolism and nutrition disorders: Hyponatraemia was added as a "Common" adverse reaction.</p> <p>[...]</p> <p><u>Description of selected serious adverse reactions</u></p> <p><i>GI-vaginal Fistulae in study GOG-0240</i></p> <p>[...]</p> <p>The frequency of GI-vaginal fistulae in the group treated with Avastin + chemotherapy was higher in patients with recurrence within the field of prior radiation (16.7%) compared with patients with no prior radiation and/ or no</p>	<p>[...]</p> <p>Table 1: Adverse Reactions by Frequency</p> <p>בעדכון עלון זה ישנה הוספת מידע חדש</p> <p style="padding-left: 40px;">common מופיע בעמודת Epistaxis</p> <p style="padding-left: 40px;">common מופיע בעמודת Myalgia</p> <p>[...]</p> <p>Table 2: Severe Adverse Reactions by Frequency</p> <p>בעדכון עלון זה ישנה הוספת מידע חדש</p> <p>[...]</p> <p><u>Description of selected serious adverse reactions</u></p> <p><i>GI-vaginal Fistulae in study GOG-0240</i></p> <p>[...]</p> <p>The frequency of GI-vaginal fistulae in the group treated with Avastin + chemotherapy was higher in patients with recurrence within the field of prior radiation (16.7%) compared with patients with recurrence outside the field</p>	<p>4.8 Undesirable effects</p>

ההחמרות המבוקשות - עלון לרופא

טקסט חדש	טקסט נוכחי	פרק בעלון
<p>recurrence inside the field of prior radiation (3.6%).</p> <p>[...]</p> <p><i>Wound healing</i></p> <p>[...]</p> <p>In clinical trials of ovarian cancer, Grade 3-5 wound healing complications were observed in up to 1.8% of patients in the bevacizumab arm versus 0.1% in the control arm (NCI-CTCAE v.3).</p> <p>[...]</p> <p><i>Proteinuria</i></p> <p>[...]</p> <p>Proteinuria ranged in severity from clinically asymptomatic, transient, trace proteinuria to nephrotic syndrome, with the great majority as Grade 1 proteinuria (NCI-CTCAE v.3). Grade 3 proteinuria was reported in up to 10.9% of treated patients.</p> <p>[...]</p>	<p>of prior radiation (3.6%).</p> <p>[...]</p> <p><i>Wound healing</i></p> <p>[...]</p> <p>In clinical trials of ovarian cancer, Grade 3-5 wound healing complications were observed in up to 1.2% of patients in the bevacizumab arm versus 0.1% in the control arm (NCI-CTCAE v.3).</p> <p>[...]</p> <p><i>Proteinuria</i></p> <p>[...]</p> <p>Proteinuria ranged in severity from clinically asymptomatic, transient, trace proteinuria to nephrotic syndrome, with the great majority as Grade 1 proteinuria (NCI-CTCAE v.3). Grade 3 proteinuria was reported in up to 8.1% of treated patients.</p> <p>[...]</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.