הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 25/11/2015

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

שם בעל הרישום: Roche Pharmaceuticals (Israel) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות - עלון לרופא		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
[…] *Proteinuria* (see section 4.8) Patients with a history of hypertension may be at increased risk for the development of proteinuria when treated with Avastin. There is evidence suggesting that all Grade (US National Cancer Institute-Common Terminology Criteria for Adverse Events [NCI-CTCAE v.3]) proteinuria may be related to the dose. Monitoring of proteinuria by dipstick urinalysis is recommended prior to starting and during therapy. Grade 4 proteinuria (nephrotic syndrome) was seen in up to 1.4% of patients treated with Avastin. Therapy should be permanently discontinued in patients who develop nephrotic syndrome (NCI-CTCAE	[…] *Proteinuria* (see section 4.8) Patients with a history of hypertension may be at increased risk for the development of proteinuria when treated with Avastin. There is evidence suggesting that all Grade (US National Cancer Institute-Common Terminology Criteria for Adverse Events [NCI-CTCAE v.3]) proteinuria may be related to the dose. Monitoring of proteinuria by dipstick urinalysis is recommended prior to starting and during therapy. Therapy should be permanently discontinued in patients who develop Grade 4 proteinuria (nephrotic syndrome) (NCI-CTCAE	**4.4 Special warnings and precautions for use**
[…] *Proteinuria* (see section 4.4) In clinical trials, proteinuria has been reported within the range of 0.7% to 38% of patients receiving Avastin. 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. Grade 4 proteinuria (nephrotic syndrome) was seen in up to 1.4% of treated patients. Testing for proteinuria is recommended prior to start of Avastin therapy. In most clinical trials urine protein levels of ≥ 2g/24 hrs led to the holding of Avastin until recovery to < 2g/24 hrs. […] Laboratory abnormalities Clinical trials have shown that	[…] *Proteinuria* (see section 4.4) In clinical trials, proteinuria has been reported within the range of 0.7% to 38% of patients receiving Avastin. 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. Grade 4 proteinuria (nephrotic syndrome) was seen in up to 1.4% of treated patients. The proteinuria seen in clinical trials was not associated with renal dysfunction and rarely required permanent discontinuation of therapy. Testing for proteinuria is recommended prior to start of Avastin therapy. In most clinical trials urine protein levels of ≥ 2g/24 hrs led to the holding of Avastin until recovery to < 2g/24 hrs.	**4.8 Undesirable effects**

ההחמרות המבוקשות - עלון לרופא		
פרק בעלון	טקסט נוכחי	טקסט חדש
		transient increases in serum creatinine (ranging between 1.5-1.9 times baseline level), both with and without proteinuria, are associated with the use of Avastin. The observed increase in serum creatinine was not associated with a higher incidence of clinical manifestations of renal impairment in patients treated with Avastin.

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: 25 בנובמבר 2015