ינואר 2026

AVASTIN®
אוואסטין

Bevacizumab 25mg/ml
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על עדכונים בעלון לרופא של התכשיר המצוין מעלה. בהודעה זו מצויינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

1. Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.

2. Avastin in combination with paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer.

3. Avastin, in addition to platinum-based chemotherapy, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

4. Avastin, in combination with erlotinib, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations.

5. Avastin in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and/or metastatic renal cell cancer.

6. Avastin, as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.

7. Avastin, in combination with carboplatin and paclitaxel, is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are at high risk for recurrence (residual disease after debulking).

8. Avastin, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents

9. Bevacizumab in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.

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10. Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for treatment of patients with persistent, recurrent, or metastatic carcinoma of the cervix.
11. Bevacizumab, in combination with atezolizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. Refer to the Prescribing Information for medicines administered in combination with bevacizumab for further information.

טקסט עם קו תחתי מציין טקסט שהוסף לעלון.

טקסט עם קו תחתי הצבוע בצהוב מציין החמרה.

~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר ע"י משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079 טלפון 09-9737777.
כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

Signed by:
lavi ami-ad
Signer Name: lavi ami-ad
Signing Reason: I approve this document
Signing Time: 28-Jan-2026 | 11:17:27 AM CET
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לביא עמי-עד

רוקח ממונה

Signed by:
Avital Weisbrot
Signer Name: Avital Weisbrot
Signing Reason: I approve this document
Signing Time: 28-Jan-2026 | 8:16:41 AM CET
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אביטל ויסברוט

מחלקת רישום

ינואר 2026

בסעיף 4.8 Undesirable Effects עודכן המידע הבא:

[…]

Table 1: Adverse reactions by frequency

System organ class	Very common	Common	Uncommon	Rare	Very rare	Frequency not known
Vascular disorders	Hypertension[b,d], Thrombo-embolism (venous)[b,d]	Thrombo-embolism (arterial)[b,d], Haemorrhage[b,d], Deep vein thrombosis				Renal thrombotic micro-angiopathy[a,b] Hyaline occlusive glomerular microangiopathy[a], Aneurysms and artery dissections

[a] For further information please refer to Table 3 'Adverse reactions reported in post-marketing setting.'

[…]

Table 2: Severe adverse reactions by frequency

System organ class	Very common	Common	Uncommon	Rare	Very rare	Frequency not known
Vascular disorders	Hypertension[a,b]	Thromboembolism arterial[a,b], Haemorrhage[a,b] Thromboembolism (venous)[a,b], Deep vein thrombosis				Renal thrombotic microangiopathy[b,c] Hyaline occlusive glomerular microangiopathy[c], Aneurysms and artery dissections

[c] For further information please refer to Table 3 'Adverse reactions reported in post-marketing setting'.

[…]

Post-marketing experience

Table 3 Adverse reactions reported in post-marketing setting

System organ class (SOC)	*Reactions (frequency*)*
Vascular disorders	Renal thrombotic microangiopathy with or without concomitant sunitinib use, and hyaline occlusive glomerular microangiopathy, which may be clinically manifested as proteinuria (not known) For further information on proteinuria see section 4.4 and *Proteinuria* in section 4.8.