

# AVASTIN®

איוסטין

## **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 מספר 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 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.
3. Avastin in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and /or metastatic renal cell cancer.
4. Avastin in combination with paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer.
5. Avastin as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.
6. 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).
7. Avastin, in combination with carboplatin and gemcitabine, is indicated for the 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.

8. Avastin (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.
9. Avastin (Bevacizumab) 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.
10. 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.
11. Avastin, 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.

הסבר:

טקסט עם קו תחתו מצוין טקסט שהוסף לעלון.

טקסט עם קו חוצה מצוין 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](http://www.roche.co.il).

ב ב ר כ ה,



לביא עמי-עד

רוקח ממונה



מאי קדים

מחלקת רישום

בסעיף **4.4 Special warnings and precautions for use** עודכן המידע הבא:

[...]

*Hypersensitivity reactions (including anaphylactic shock)/infusion reactions (see section 4.8)* Patients may be at risk of developing infusion/hypersensitivity reactions **(including anaphylactic shock)**. Close observation of the patient during and following the administration of bevacizumab is recommended as expected for any infusion of a therapeutic humanised monoclonal antibody. If a reaction occurs, the infusion should be discontinued and appropriate medical therapies should be administered. A systematic premedication is not warranted.

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
Immune system disorders		Hypersensitivity, infusion reactions <sup>a,b,d</sup>		<b>Anaphylactic shock</b>		

[...]

**Table 2: Severe Adverse Reactions by Frequency**

[...]

System organ class	Very Common	Common	Uncommon	Rare	Very Rare	Frequency Not Known
Immune system disorders		<b>Hypersensitivity, infusion reactions<sup>a,b,c</sup></b>		<b>Anaphylactic shock</b>		<b>Hypersensitivity, infusion reactions<sup>a,b,e</sup></b>

[...]

*Hypersensitivity reactions (including anaphylactic shock)/infusion reactions (see section 4.4 and Post-marketing experience below)* In some clinical trials anaphylactic and anaphylactoid-type reactions

were reported more frequently in patients receiving Avastin in combination with chemotherapy than with chemotherapy alone. The incidence of these reactions in some clinical trials of Avastin is common (up to 5% in bevacizumab-treated patients).

[...]

**Table 3 Adverse reactions reported in post-marketing setting**

[...]

<i>System organ class (SOC)</i>	<i>Reactions (frequency*)</i>
<i>Immune system disorders</i>	Hypersensitivity reactions and infusion reactions ( <b>common</b> <del>not known</del> ); with the following possible co-manifestations: dyspnoea/difficulty breathing, flushing/redness/rash, hypotension or hypertension, oxygen desaturation, chest pain, rigors and nausea/vomiting (see also section 4.4 and Hypersensitivity reactions/infusion reactions above). <b>Anaphylactic shock (rare) (see also section 4.4).</b>

[...]

בסעיף **5.1 Pharmacodynamic properties** עודכן המידע הבא:

Pharmacotherapeutic group: antineoplastic and immunomodulating agents, antineoplastic agents, ~~other antineoplastic agents~~, monoclonal antibodies and antibody drug conjugates, ATC code: LOIFG01.

[...]