

AVASTIN®

אווסטין

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.

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,



לביא עמי-עד

רוקח ממונה



אביטל ויסברוט

מחלקת רישום

בסעיף 2. Qualitative and Quantitative Composition עודכן המידע הבא:

[...]

Excipient with known effectEach 4 ml vial contains 1.6 mg of polysorbate 20.Each 16 ml vial contains 6.4 mg of polysorbate 20.**בסעיף 4.4 Special warnings and precautions for use עודכן המידע הבא:**

[...]

Important information about some of the ingredients of Avastin Excipients

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

This medicine contains 1.6 mg of polysorbate 20 in each 100 mg/4 ml vial and 6.4 mg in each 400 mg/16 ml vial which is equivalent to 0.4 mg/ml. Polysorbates may cause allergic reactions.

בסעיף 5.1 Pharmacodynamic properties עודכן המידע הבא:

[...]

Clinical efficacy and safety

Metastatic carcinoma of the colon or rectum (mCRC)

The safety and efficacy of the recommended dose (5 mg/kg of body weight every two weeks) in metastatic carcinoma of the colon or rectum were studied in three randomised, active-controlled clinical trials in combination with fluoropyrimidine-based first-line chemotherapy. Avastin was combined with two chemotherapy regimens:

[...]