

# AVASTIN<sup>®</sup>

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 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 מציינ טקסט שהוסף לעלון.

~~טקסט עם קו חוצה~~ מציינ 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 **4.2 Posology and method of administration** עודכן המידע הבא:

Do not shake the vial.

[...]

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

[...]

**Important information about some of the ingredients of Avastin**

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

בסעיף **6.6 Special precautions for disposal and other handling** עודכן המידע הבא:

Do not shake the vial.

[...]