AVASTIN®
אוווסטין

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 שנעשו בעלון לרופא של התכשיר.
לתשומת ליבכם, בהודעה זו מצוינים 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. Bevacizumab, 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.

הסבר:
טקסט עם קו תחתי מציין טקסט שהוסף לעלון.
~~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,

בת אל כהן
רוקחת ממונה

לביא עמי-עד
רוקח ממונה

עדכונים מהותיים בעלון לרופא

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

[…]

Aneurysms and artery dissections

The use of VEGF pathway inhibitors in patients with or without hypertension may promote the formation of aneurysms and/or artery dissections. Before initiating Avastin, this risk should be carefully considered in patients with risk factors such as hypertension or history of aneurysm.

[…]

בסעיף 4.8 Undesirable effects עודכן המידע הבא:

[…]

Table 1: Adverse Reactions by Frequency

Vascular disorders: Aneurysms and artery dissections has been added at Frequency Not Known (cannot be estimated from the available data)

[…]

Table 2: Severe Adverse Reactions by Frequency

Vascular disorders: Aneurysms and artery dissections has been added at Frequency Not Known (cannot be estimated from the available data)

[…]

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:https://sideeffects.health.gov.il/ ~~(http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).~~