



פברואר 2021

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 רישום התוויה נוספת לתכשיר אווסטין, בשילוב עם טיסנזומב (atezolizumab), לטיפול בסרטן כבד גרורתי או שלא ניתן לנתחו במטופלים אשר לא קיבלו טיפול סיסטמי קודם.

נוסח ההתוויה המלא הינו כדלקמן:

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.

כמו כן, 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.
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.

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 ,

לביא עמי-עד
רוקח ממונה

בת אל כהן
רוקחת ממונה

עדכונים מהותיים בעלון לרופא

בסעיף **4.1 Therapeutic indications** עודכן המידע הבא:

[...]

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.

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

[...]

Paediatric population

[...]

Soft tissue sarcoma

In a randomized phase II study (BO20924) a total of 154 patients aged ≥ 6 months to <18 years with newly diagnosed metastatic rhabdomyosarcoma and non-rhabdomyosarcoma soft tissue sarcoma were treated with standard of care (Induction IVADO/IVA+/- local therapy followed by Maintenance Vinorelbine and cyclophosphamide) with or without bevacizumab (2.5 mg/kg/week) for a total duration of treatment of approximately 18 months. At the time of the final primary analysis, the primary endpoint of EFS by independent central review did not show a statistically significant difference between the two treatment arms, with HR of 0.93 (95% CI: 0.61, 1.41; p-value = 0.72).

The difference in ORR per independent central review was 18% (CI: 0.6%, 35.3%) between the two treatment arms in the few patients who had evaluable tumor at baseline and had a confirmed response prior to receiving any local therapy: 27/75 patients (36.0%, 95% CI: 25.2%, 47.9%) in the Chemo arm and 34/63 patients (54.0%, 95% CI: 40.9%, 66.6%) in the Bv + Chemo arm.

The final Overall Survival (OS) analyses showed no significant clinical benefit from addition of bevacizumab to chemotherapy in this patient population.

~~The secondary endpoint of Overall Survival (OS) was not mature. Until mature OS results and safety data are available no definitive conclusion can be drawn on the benefit/risk balance.~~

Addition of Avastin to standard of care did not demonstrate clinical benefit in clinical trial BO20924, in 71 evaluable children (from age 6 months to less than 18 years old) patients with metastatic Rhabdomyosarcoma and non-Rhabdomyosarcoma Soft Tissue Sarcoma (see section 4.2 for information on paediatric use).

[...]

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

Avastin should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared solution. A sterile needle and syringe should be used to prepare Avastin.

[...]