

May 2025

Mvasi (bevacizumab 25 mg/mL) concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא של התכשיר **Mvasi**. בהודעה זו מפורטים השינויים המשמעותיים. קו תחתי מציין תוספת טקסט, קו חוצה מציין מחיקה.

ההתוויות המאושרות:

- MVASI in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum.
- MVASI in addition to platinum - based chemotherapy is indicated for first - line treatment of adult patients with unresectable advanced metastatic or recurrent non- small cell lung cancer other than predominantly squamous cell histology.
- MVASI in combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer.
- MVASI in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer.
- MVASI as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.
- MVASI in combination with carboplatin and paclitaxel, is indicated for the front-line treatment of advanced (FIGO stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer in adult patients who are at high risk for recurrence (residual disease after debulking).
- MVASI 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.
- MVASI 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.
- MVASI in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated, in patients who cannot receive platinum therapy, for treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.
- MVASI, 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.

2. Quantitative and Qualitative Composition

[...]

Excipient with known effect

Each 4 ml vial contains 1.6 mg of polysorbate 20.

Each 16 ml vial contains 6.4 mg of polysorbate 20.

4.4 Special warnings and precautions for use

[...]

~~Important information about some of the ingredients of Mvasi~~ 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.

5.1 Pharmacodynamic properties

[...]

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:

[...]

העלון לרופא נשלח לפרסום במאגר התרופות של אתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שרות לקוחות: Medison-CS@medison.co.il טלפון: *5634

בברכה,
חברת אמג'ן