אוגוסט 2022

MVASI (Bevacizumab)

Powder for concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעכם על עדכונים בעלון לרופא לתכשיר אמווסי.

בהודעה זו מצויינים השינויים העיקריים בלבד.

<u>ההתוויות המאושרות:</u>

1. MVASI in combination with fluoropyrimidine-based chemotherapy is indicated for treatmentof adult patients with metastatic carcinoma of the colon or rectum.
2. MVASI in addition to platinum - based chemotherapy is indicated for first - line treatment ofadult patients with unresectable advanced metastatic or recurrent non- small cell lung cancer other than predominantly squamous cell histology.
3. MVASI in combination with interferon alfa-2a is indicated for first line treatment of adultpatients with advanced and/or metastatic renal cell cancer.
4. MVASI in combination with paclitaxel is indicated for first-line treatment of adult patientswith metastatic breast cancer.
5. MVASI as a single agent, is indicated for the treatment of glioblastoma in patients withprogressive disease following prior therapy.
6. 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).
7. 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 orprimary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.
8. 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.
9. 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.
10. MVASI, in combination with erlotinib, is indicated for first-line treatment of adult patientswith unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations.

<u>עדכונים מהותיים בעלון לרופא:</u>

4.2 Posology and method of administration

<u>Do not shake the vial.</u>

[...]

4.4 Special warnings and precautions for use

[...]

Important information about some of the ingredients of MVASI

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

~~Sodium content~~
~~*MVASI 25 mg/mL concentrate for solution for infusion (4 mL)*~~

~~This medicinal product contains 5.4 mg sodium per 4 mL vial, equivalent to 0.3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.~~

~~*MVASI 25 mg/mL concentrate for solution for infusion (16 mL)*~~

~~This medicinal product contains 21.7 mg sodium per 16 mL vial, equivalent to 1.1% of the WHO recommended maximum daily intake of 2 g sodium for an adult.~~

6.6 Special precautions for disposal and other handling

Do not shake the vial.
[...]

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, ניתן לקבלו גם על-ידי פניה למפיץ המקומי: חברת נובלוג.

לפרטים ולהזמנות:

- טלפון: 054-2456220
- מייל: Sales@medomie.co.il

בברכה,

סיגל בן דור

רוקחת ממונה
ומנהלת רגולציה