פברואר 2023

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.

ההתוויות המאושרות:

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.

עדכונים מהותיים בעלון לרופא:

4.4 Special warnings and precautions for use

[...]

Hypersensitivity reactions (including anaphylactic shock)/infusion reactions (see section 4.8)
Patients may be at risk of developing infusion/hypersensitivity reactions (including anaphylactic shock). Close observation of the patient during and following the administration of bevacizumab is recommended as expected for any infusion of a therapeutic humanized monoclonal antibody. If a

reaction occurs, the infusion should be discontinued and appropriate medical therapies should be administered. A systematic premedication is not warranted.

4.8 Undesirable effects

[...]

Table 1: Adverse reactions by frequency

[...]

System organ class	Very common	Common	Uncommon	Rare	Very rare	Frequency not known
Immune system disorders		Hypersensitivity, Infusion reactions[a,b,d]		Anaphylactic shock		

[...]

Table 2. Severe adverse reactions by frequency

[...]

System organ class	Very common	Common	Uncommon	Rare	Very rare	Frequency not known
Immune system disorders		Hypersensitivity, Infusion reactions[a,b,c]		Anaphylactic shock		~~Hypersensitivity, Infusion reactions[a,b,c]~~

[...]

Hypersensitivity reactions (including anaphylactic shock)/infusion reactions (see section 4.4 and Post-marketing experience below)

In some clinical trials anaphylactic and anaphylactoid-type reactions were reported more frequently in patients receiving bevacizumab in combination with chemotherapy than with chemotherapy alone. The incidence of these reactions in some clinical trials of bevacizumab is common (up to 5% in bevacizumab-treated patients).

[...]

Table 3. Adverse reactions reported in post-marketing setting

[...]

System organ class (SOC)	Reactions (frequency*)
Immune system disorders	Hypersensitivity reactions and infusion reactions (~~not known~~ common); with the following possible co-manifestations: dyspnea/difficulty breathing, flushing/redness/rash, hypotension or hypertension, oxygen desaturation, chest pain, rigors and nausea/vomiting (see also section 4.4 and Hypersensitivity reactions (including anaphylactic shock)/infusion reactions above). Anaphylactic shock (rare) (see also section 4.4).

[...]

5.1 Pharmacodynamic properties

[...]

Pharmacotherapeutic group: antineoplastic and immunomodulating agents, antineoplastic agents, ~~other antineoplastic agents,~~ monoclonal antibodies and antibody drug conjugates, ATC code: L01FG01.

[...]

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