

יולי 2025

## **Abevmy, 25 mg/ml concentrate for solution for infusion**

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר **אבוומי**.

בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלונים.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

### **הרכב התכשיר:**

Each ml of concentrate contains 25 mg of bevacizumab

### **התוויות מאושרות:**

Abevmy in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.

Abevmy in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer.

Abevmy, 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.

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.

Abevmy in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and/or metastatic renal cell cancer.

Abevmy, as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.

Abevmy, 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).

Abevmy, in combination with carboplatin and gemcitabine, is indicated for 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.

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.

Abevmy, (bevacizumab) in combination with paclitaxel and cisplatin or, paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic carcinoma of the cervix.

העלון לרופא עודכן בתאריך יולי 2025. להלן העדכון המהווה החמרה במידע הבטיחותי (מסומן באדום):

#### **4. CLINICAL PARTICULARS**

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#### **4.4 Special warnings and precautions for use – Important information about some of the ingredients of Abevmy**

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##### ***Abevmy contains polysorbate***

This medicinal product contains 1.6 mg of polysorbate 20 in each 100 mg/4 mL vial and 6.4 mg of polysorbate 20 in each 400 mg/16 mL vial, which is equivalent to 0.4 mg/ml.

Polysorbates may cause allergic reactions.