פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

ספטמבר 2025

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכונים בעלון לרופא של התכשיר: **Zirabev**

חוזק:

Each 4 ml vial contains 100 mg of bevacizumab.
Each 16 ml vial contains 400 mg of bevacizumab.

התוויה:

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

Zirabev in combination with paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer. For further information as to human epidermal growth factor receptor 2 (HER2) status.

Zirabev, 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.

Zirabev, 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.

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

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

Zirabev, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynecology and Obstetrics (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).

Zirabev, 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.

Zirabev 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.

Zirabev, 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.

להלן העדכונים העיקריים בעלון לרופא:

Qualitative and quantitative composition

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Excipients with known effect

Each 4 ml vial contains 3.0 mg of sodium and 0.8 mg of polysorbate 80.

Each 16 ml vial contains 12.1 mg of sodium and 3.2 mg of polysorbate 80.

Special warnings and precautions for use

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Excipients ~~information~~

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Polysorbate

This medicine contains 0.8 mg of polysorbate 80 in each 100 mg/4 ml vial and 3.2 mg in each 400 mg/16 ml vial which is equivalent to 0.2 mg/ml. Polysorbates may cause allergic reactions.

5.1 Pharmacodynamic properties

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Clinical efficacy and safety

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725.

בברכה,
גילי קבשה
רוקחת ממונה