Public Summary

Summary for ARTG Entry: 309320 ZIRABEV bevacizumab 100 mg/ 4 mL concentrated solution for injection vial

ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	Level 17 151 Clarence Street, Sydney, NSW, 2000 Australia
ARTG Start Date	21/11/2019
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. ZIRABEV bevacizumab 100 mg/ 4 mL concentrated solution for injection vial

Product Type Single Medicine Product **Effective date** 21/11/2019

Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Metastatic Colorectal Cancer,ZIRABEV (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for the treatment of patients with metastatic colorectal cancer.,Locally recurrent or metastatic Breast Cancer,ZIRABEV (bevacizumab) in combination with paclitaxel is indicated for the first-line treatment of metastatic breast cancer in patients in whom an anthracycline-based therapy is contraindicated.,Advanced, metastatic or recurrent non-squamous Non-Small Cell Lung Cancer (NSCLC),ZIRABEV (bevacizumab), in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent, non-squamous, non- small cell lung cancer.,Advanced and/or metastatic Renal Cell Cancer,ZIRABEV (bevacizumab) in combination with interferon alfa-2a is indicated for treatment of patients with advanced and/or metastatic renal cell cancer.,Grade IV Glioma,ZIRABEV (bevacizumab) as a single agent, is indicated for the treatment of patients with Grade IV glioma after relapse or disease progression after standard therapy, including chemotherapy.,Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer,ZIRABEV (bevacizumab) in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with advanced (FIGO stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.,Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer,ZIRABEV (bevacizumab), in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, is indicated for the treatment of patients with first recurrence of platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors.,ZIRABEV (bevacizumab) in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received no more than two prior chemotherapy regimens, and have not received any prior anti-angiogenic therapy including bevacizumab.,Cervical Cancer,ZIRABEV (bevacizumab) in combination with paclitaxel and cisplatin is indicated for the treatment of persistent, recurrent or metastatic carcinoma of the cervix. ZIRABEV (bevacizumab) in combination with paclitaxel and topotecan is an acceptable alternative where cisplatin is not tolerated or not indicated.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	36 Months	Store at 2 to 8 degrees Celsius	Not recorded	Refrigerate Do not Freeze Do not Shake Protect from Light

Pack Size/Poison information

Pack Size

1

Poison Schedule

(S4) Prescription Only Medicine

Components

1. ZIRABEV bevacizumab 100 mg/ 4 mL concentrated solution for injection vial

Dosage Form	Injection, concentrated
Route of Administration	Intravenous Infusion
Visual Identification	Clear to slightly opalescent, colourless to pale brown, sterile solution.

Active Ingredients	
Bevacizumab	**100 mg**

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