



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	334816	ABEVMY bevacizumab 100 mg/4 mL concentrate injection for solution vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Alphapharm Pty Ltd	
<b>Postal Address</b>	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
<b>ARTG Start Date</b>	6/09/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . ABEVMY bevacizumab 100 mg/4 mL concentrate injection for solution vial**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/09/2021
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Metastatic Colorectal Cancer, ABEVMY (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for the treatment of patients with metastatic colorectal cancer. Locally recurrent or metastatic Breast Cancer, ABEVMY (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 (see section 5.1 PHARMACODYNAMIC PROPERTIES, Clinical Trials). Advanced, metastatic or recurrent non-squamous Non-Small Cell Lung Cancer (NSCLC), ABEVMY (bevacizumab), in combination with carboplatin and paclitaxel, is indicated for firstline treatment of patients with unresectable advanced, metastatic or recurrent, non-squamous, non- small cell lung cancer. Advanced and/or metastatic Renal Cell Cancer, ABEVMY (bevacizumab) in combination with interferon alfa-2a is indicated for treatment of patients with advanced and/or metastatic renal cell cancer. Grade IV Glioma, ABEVMY (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, ABEVMY (bevacizumab) in combination with carboplatin and paclitaxel, is indicated for firstline 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, ABEVMY (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. ABEVMY (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, ABEVMY (bevacizumab) in combination with paclitaxel and cisplatin is indicated for the treatment of persistent, recurrent or metastatic carcinoma of the cervix. ABEVMY (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	24 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Refrigerate Do not Freeze

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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1 vial

(S4) Prescription Only Medicine

**Components**

1 . ABEVMY bevacizumab 100 mg/4 mL concentrate injection for solution vial

<b>Dosage Form</b>	Injection, concentrated
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	A clear to slightly opalescent, colourless to pale brown, sterile solution

**Active Ingredients**

<b>Bevacizumab</b>	<b>100 mg</b>
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**Other Ingredients (Excipients)**

dibasic sodium phosphate  
monobasic sodium phosphate dihydrate  
phosphoric acid  
polysorbate 20  
sodium hydroxide  
trehalose dihydrate  
water for injections

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