



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	99757	AVASTIN bevacizumab 400mg/16mL injection vial
ARTG entry for	Medicine Registered	
Sponsor	Roche Products Pty Ltd	
Postal Address	PO Box 255, DEE WHY, NSW, 2099 Australia	
ARTG Start Date	24/02/2005	
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 . AVASTIN bevacizumab 400mg/16mL injection vial

Product Type	Single Medicine Product	Effective Date	17/05/2021
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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
AVASTIN (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for the treatment of patients with metastatic colorectal cancer.
- Locally recurrent or metastatic Breast Cancer
AVASTIN (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 Clinical Trials).
- Advanced, metastatic or recurrent non-squamous Non-Small Cell Lung Cancer (NSCLC)
AVASTIN (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
AVASTIN (bevacizumab) in combination with interferon alfa-2a is indicated for treatment of patients with advanced and/or metastatic renal cell cancer
- Grade IV Glioma
AVASTIN (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
AVASTIN (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
AVASTIN (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.
- AVASTIN (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
AVASTIN (bevacizumab) in combination with paclitaxel and cisplatin is indicated for the treatment of persistent, recurrent or metastatic carcinoma of the cervix. AVASTIN (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



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

Pack Size/Poison information

Pack Size	Poison Schedule
1 Vial	(S4) Prescription Only Medicine

Components

1 . AVASTIN bevacizumab 400mg/16mL injection vial

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

Active Ingredients

Bevacizumab	400 mg
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Other Ingredients (Excipients)

dibasic sodium phosphate heptahydrate
monobasic sodium phosphate monohydrate
polysorbate 20
trehalose dihydrate
water for injections

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