Bevixa™

Bevacizumab solution for IV infusion

Presentation

Bevixa™ 100 IV infusion: Each vial contains Bevacizumab INN 100 mg in 4 ml sterile solution for IV infusion

Bevixa™ 400 IV infusion: Each vial contains Bevacizumab INN 400 mg in 16 ml sterile solution for IV infusion

Description

Bevacizumab is a sterile solution for intravenous infusion. It is a recombinant humanized monoclonal IgG1 antibody that binds to and inhibits the biologic activity of human vascular endothelial growth factor (VEGF) in in vitro and in vivo assay systems.

Indications and Uses

Bevacizumab is a vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treatment of

- Metastatic colorectal cancer, with intravenous 5-fluorouracil–based chemotherapy for first- or second-line treatment
- Metastatic colorectal cancer, with fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based
- chemotherapy for second-line treatment in patients who have progressed on a first-line Bevacizumab containing regimen
- Non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease.
- Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy
- Effectiveness based on improvement in objective response rate. No data available demonstrating improvement in disease-related symptoms or survival with Bevacizumab.
- Metastatic renal cell carcinoma with interferon alfa
- Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease
- Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan

Limitation of Use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

Dosage and Administration

Bevacizumab should not be administered as an IV push or bolus

Bevacizumab should not be initiated for 28 days following major surgery and until surgical wound is fully healed

- Metastatic colorectal cancer
  - 5 mg/kg IV every 2 weeks with bolus-IFL
  - 10 mg/kg IV every 2 weeks with FOLFOX4
  - 5 mg/kg IV every 2 weeks or 7.5 mg/kg IV every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first-line Bevacizumab containing regimen
- Non-squamous non-small cell lung cancer
  - 15 mg/kg IV every 3 weeks with carboplatin/paclitaxel

  Glioblastoma
  - 10 mg/kg IV every 2 weeks
- Metastatic renal cell carcinoma (mRCC)
  - 10 mg/kg IV every 2 weeks with interferon alfa
- Persistent, recurrent, or metastatic carcinoma of the cervix
  - 15 mg/kg IV every 3 weeks with paclitaxel/cisplatin or paclitaxel/topotecan
- Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer
  - 10 mg/kg IV every 2 weeks with paclitaxel, pegylated liposomal doxorubicin or weekly topotecan
  - 15 mg/kg IV every 3 weeks with topotecan given every 3 weeks

Side-effects

Most common adverse reactions incidence (> 10% and at least twice the control arm rate) are epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis. Some of the adverse reactions are commonly seen with chemotherapy; however, Bevacizumab may exacerbate these reactions when combined with chemotherapeutic agents. Examples include palmar-plantar erythrodysaesthesia syndrome with pegylated liposomal doxorubicin or capecitabine peripheral sensory neuropathy with paclitaxel or oxaliplatin, and nail disorders or alopecia with paclitaxel.

Contraindications

None

Precaution

- Perforation or Fistula: Bevacizumab should be discontinued if perforation or fistula occurs.
- Arterial Thromboembolic Events (e.g., myocardial infarction, cerebral infarction): Bevacizumab should be discontinued for severe ATE.
- Venous Thromboembolic Events: Bevacizumab should be discontinued for life-threatening VTE
- Hypertension: Monitor blood pressure and treat hypertension. Temporarily suspend Avastin if not medically controlled. Bevacizumab should be discontinued for hypertensive crisis or hypertensive encephalopathy
- Posterior Reversible Encephalopathy Syndrome (PRES): Bevacizumab should be discontinued
- Proteinuria: Urine protein should be monitored. Bevacizumab should be discontinued for nephrotic syndrome. Bevacizumab should be temporarily discontinued for moderate proteinuria.
- Infusion Reactions: Bevacizumab should be stopped in case of severe infusion reactions.

  Embryo-fetal Toxicity: Females should be adviced of potential risk to a fetus and the need for use of effective contraception
- Ovarian Failure: Females should be adviced of the potential risk

Pregnancy and Lactation

Bevacizumab may cause fetal harm based on findings from animal studies and the drug's mechanism of action. Pregnant women should be advised of the potential risk to a fetus.

Lactation

No data are available regarding the presence of Bevacizumab in human milk, the effects on the breast fed infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from Bevacizumab, nursing woman should be advised that breastfeeding is not recommended during treatment with Bevacizumab.

Pediatric Use

Safety and effectiveness of Bevacizumab have not been established in pediatric patients.

Drug interactions

A drug interaction study was performed in which Irinotecan was administered as part of the FOLFIRI regimen with or without Bevacizumab. The results demonstrated no significant effect of Bevacizumab on the pharmacokinetics of Irinotecan or its active metabolite SN38.

Commercial pack

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Bevixa™ 400 IV infusion: Each box contains 1 vial of Bevacizumab 400 mg in 16 ml sterile solution for IV infusion.

Manufactured by
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V.N.01

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