

BEVANEAL™ 100

Bevacizumab 100 mg/4 ml

Presentation: Each 1 ml of vial contains: Bevacizumab Drug Substance In-House...25.0 mg/ml, α, α - trehalose dehydrate EP...60.0 mg/ml, Sodium Phosphate (monobasic monohydrate) IP...5.8 mg/ml, Sodium Phosphate (dibasic anhydrous) EP...1.2 mg/ml, Polysorbate 20 IP...0.4 mg/ml, Sodium Hydroxide IP...q.s to pH 6.2, Water for injection IP...q.s to 1 ml

Colour: Clear to slightly opalescent, colourless to pale brown liquid.

BEVANEAL™ 400

Bevacizumab 400 mg/16 ml

Presentation: Each 1 ml of vial contains: Bevacizumab Drug Substance In-House 25.0 mg/ml, α, α - trehalose dehydrate EP 60.0 mg/ml, Sodium Phosphate (monobasic monohydrate) IP...5.8 mg/ml, Sodium Phosphate (dibasic anhydrous) EP...1.2 mg/ml, Polysorbate 20 IP 0.4 mg/ml, Sodium Hydroxide IP...q.s to pH 6.2, Water for injection IP...q.s to 1 ml,

Colour: Clear to slightly opalescent, colourless to pale brown liquid.

Pharmaceutical form: Solution for Infusion

Indications: (1) Metastatic colorectal cancer (2) Metastatic breast cancer (3) Non-squamous non-small cell lung cancer (4) Advance/metastatic renal cell carcinoma (5) Epithelial ovarian, fallopian tube, or primary peritoneal cancer (6) Cervical cancer (7) Glioblastoma (8) Hepatocellular carcinoma.

Dosage and administration: Do not shake the vial. Bevacizumab must be administered under the supervision of a physician experienced in the use of antineoplastic medicinal products. The initial dose should be delivered over 90 minutes as an intravenous infusion. If the first infusion is well tolerated, the second infusion may be administered over 60 minutes. If the 60-minute infusion is well tolerated, all subsequent infusions may be administered over 30 minutes. It should not be administered as an intravenous push or bolus.

Method of administration: Intravenous infusion.

Contraindications: Hypersensitivity to active substance or to any of the excipients used in the formulation. Hypersensitivity to other human or humanized antibodies. Pregnancy

Warnings & precautions: Traceability, Gastrointestinal (GI) perforation and fistulae, GI- vaginal Fistulae , Non-GI Fistulae, Wound healing complications , Hypertension , Monitoring of blood pressure is generally recommended during therapy, Posterior Reversible Encephalopathy Syndrome, Proteinuria, Arterial thromboembolism, Venous thromboembolism, Haemorrhage, Pulmonary haemorrhage/haemoptysis, Aneurysms and artery dissections, Congestive heart failure, Neutropenia and infection, hypersensitivity reaction/infusion reactions, Osteonecrosis of the jaw, Eye disorder, systemic effects following intravitreal use, Ovarian failure/fertility.

Drug interaction: Effect of other medicinal products on bevacizumab antineoplastic agents, sunitinib malate, platinum- or taxane-based therapies and Radiotherapy.

Pregnancy & lactation: Pregnancy There are no clinical trial data on the use of Bevacizumab in pregnant women. Studies in animals have shown reproductive toxicity including malformations. Women of childbearing potential have to use effective contraception during (and up to 6 months after) treatment. Breastfeeding It is not known whether bevacizumab is excreted in human milk. As maternal IgG is excreted in milk and bevacizumab could harm infant growth and development, women must discontinue breast-feeding during therapy and not breast-feed for at least six months following the last dose of Bevacizumab.

Symptoms and treatment of overdose: The highest dose tested in humans (20 mg/kg of body weight, intravenous every 2 weeks) was associated with severe migraine in several patients.

Storage: Store in a refrigerator (2°C-8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light. Do not shake the vial.

Pack size: 4 ml solution in a vial (Type I glass) with a stopper (Bromobutyl rubber) containing 100 mg of bevacizumab. 16 ml solution in a vial (Type I glass) with a stopper (Bromobutyl rubber) containing 400 mg of bevacizumab. Pack of 1 vial.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited Regd. Office: 9th Floor, 901 to 905, Iscon Elegance, Circle P, S.G. Highway, Ahmedabad – 380015.

To be sold by retail on the prescription of an Oncologist only.