BEVAAS
(Bevacizumab)

Bevacizumab is a recombinant humanized antibody directed against vascular endothelial growth factor (VEGF), which is composed of two heavy chains (HC; 453 amino acid residues) and light chains (LC; 214 amino acid residues) with a total molecular weight of approximately 149 KDa. Bevacizumab HC contains one N-linked glycosylation site at asparagine 303 (Asn303).
The oligosaccharides are of complex biantennary structures with a core fucose and with the two branches terminating mainly with zero (G0), one (G1), or two (G2) galactose residues. Each light chain is covalently coupled through a disulfide bond at cysteine 214 to a heavy chain at cysteine 226.
The two heavy chains are covalently coupled to each other through two inter-chain disulfide bonds, which is consistent with the structure of a human IgG1.

Dosage Form

Single-use vial for injection.

Clinical Pharmacology – Mechanism of Action

Bevacizumab is a recombinant humanized monoclonal antibody that binds to vascular endothelial growth factor A (VEGF-A) isoforms, resulting in inhibition of the binding of these VEGF-A isoforms to VEGF receptors.
This prevents angiogenesis and thus results in the reduction of progression of tumor growth and metastasis.
Bevacizumab also binds to the neonatal Fc receptor (FcRn), which is important for its pK properties.

Indication

Bevacizumab is indicated for the following:

- Metastatic colorectal cancer, with intravenous 5-fluorouracil–based chemotherapy for first- or second-line treatment.
- Non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for the first-line treatment of unresectable, locally advanced, recurrent, or metastatic disease.
- Metastatic breast cancer, with paclitaxel for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer.

o Bevacizumab in combination with capecitabine is indicated for the first-line treatment of adult patients with metastatic breast cancer in whom treatment with other chemotherapy options, including taxanes or anthracyclines, is not considered appropriate.

o Bevacizumab is administered in combination with one of the following agents – paclitaxel, topotecan (given weekly), or pegylated liposomal doxorubicin for the treatment of platinum-resistant recurrent disease.

o Bevacizumab, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel, 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 therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.

Dosage and Administration

Injection in 100 mg/4 mL and 400 mg/16 mL.

Storage and Handling

Bevaas should be stored at 2 – 8°C.

Packaging Information

100 mg/4 mL: 6 mL clear glass vials (USP type 1) with 20 mm chlorobutyl rubber stoppers as a primary packaging material are used to fill the bevacizumab drug product.
400 mg/16 mL: 20 mL clear glass vials (USP type 1) with 20 mm chlorobutyl rubber stoppers as a primary packaging material are used to fill the bevacizumab drug product.

Manufactured By

M/s. Hetero Biopharma Limited,
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