BEVAKALP

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

Abbreviated Prescribing information for BEVAKALP (Bevacizumab 25 mg/mL concentrate for solution for infusion**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Bevacizumab binds to vascular endothelial growth factor (VEGF), the key driver of vasculogenesis and angiogenesis, and thereby inhibits the binding of VEGF to its receptors, Flt-1 (VEGFR-1) and KDR (VEGFR-2), on the surface of endothelial cells. Neutralising the biological activity of VEGF regresses the vascularisation of tumours, normalises remaining tumour vasculature, and inhibits the formation of new tumour vasculature, thereby inhibiting tumour growth

INDICATION: Metastatic Colorectal Cancer- Bevacizumab in combination with fluoropyrimidine-based chemotherapy is indicated for the treatment of adult patients with metastatic carcinoma of the colon or rectum. Metastatic colorectal cancer, in combination with fluoropyrimidine irinotecan or fluoropyrimidine- oxaliplatin- based chemotherapy for second-line treatment in patients who have progressed on a first-line Bevacizumab-containing regimen. **Metastatjc Breast Cancer** -Bevacizumab in combination with paclitaxel is indicated for the first-line treatment of adult patients with metastatic breast cancer Bevacizumab in combination with capecitabine is indicated for the first line treatment of adult patients with metastatic breast cancer where other chemotherapy options such as taxanes or anthracyclines are not considered appropriate.Patients who have received taxane and anthracycline containing regimens in the adjuvant setting within the last 12months should be excluded from treatment with Bevacizumab in combination with capecitabine. . **Non-Squamous Non-Small Cell Lung Cancer**- In addition to platinum-based chemotherapy is indicated for the treatment of adult patient for the first-line treatment of unrespectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer. **Advance/ metastatic renal cell carcinoma-**In combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer. **Epithelial Ovarian Fallopian Tube or Primary Peritoneal Cancer -**Bevacizumab in combination with carboplatin and paclitaxel is indicated for the front-line treatment of patients with advanced FIGO (International Federation of Gynecology and Obstetrics) stages i.e., Ill 8, 111 C and IV, of epithelial ovarian, fallopian tube or primary peritoneal cancer. Bevacizumab either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Bevacizumab as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. Bevacizumab in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. **Cervical cancer-** Bevacizumab in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix **Glioblastoma-** Bevacizumab is indicated as a single agent therapy for the treatment of glioblastoma with progressive disease in adult patients following prior therapy. **Hepatocellular carcinoma-** Hepatocellular carcinoma (HCC) in combination with atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

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.

CONTRAINDICATION: Hypersensitivity to Bevacizumab (active ingredient) or any of the excipients. Hypersensitivity to Chinese Hamster Ovary (CHO) cell products or other recombinant human or humanised antibodies. Pregnancy.

WARNINGS & PRECAUTIONS: Gastrointestinal (GI) perforations and Fistulae, GI-vaginal Fistulae, Non-GI Fistulae, Wound healing and Surgery complications, Hypertension, Monitoring of

blood pressure is generally recommended during therapy, Posterior Reversible Encephalopathy Syndrome (PRES), Proteinuria, Arterial and Venous Thromboembolism, Hemorrhage, Pulmonary hemorrhage/hemoptysis, Congestive heart failure (CHF), Neutropenia and infections, Hypersensitivity reactions/infusion reactions, Systemic effects following intravitreal use, Eye Disorder, Osteonecrosis of the jaw (ONJ), Ovarian failure/fertility.

DRUG INTERACTION: Combination of Bevacizumab and sunitinib malate, Combination with platinum- or taxane-based therapies, Radiotherapy, EGFR monoclonal antibodies in combination with Bevacizumab chemotherapy regimens.

ADVERSE REACTIONS: Gastrointestinal perforations, Haemorrhage, including pulmonary haemorrhage/haemoptysis, which is more common in non- small cell lung cancer patient, Arterial thromboembolism, Sepsis, Abscess, Cellulitis, Infection, Urinary tract infection, Necrotising fasciitis, Febrile neutropenia, Leucopenia, Neutropeniab, Thrombocytopenia, Anaemia, Lymphopenia, Hypersensitivity, infusion reactions, Anorexia, Hypomagnesaemia, Hyponatraemia, Dehydration, Peripheral sensory neuropathic, Dysarthria, Headache, Dysguesia, Cerebrovascular accident, Syncope, Somnolence, Posterior reversible encephalopathy syndrome, Hypertensive encephalopathy, Eye disorder, Lacrimation increased, Congestive heart failure, Supraventricular tachycardia, Hypertension, Thrombo-embolism (venous), Thrombose-embolism (arterial), Haemorrhage, Deep vein thrombosis, Renal thrombotic microangiopathy, Dyspnoea, Rhinitis, Epistaxis, Cough, Pulmonary haemorrhage/ Haemoptysis, Pulmonary embolism, Hypoxia, Dysphonia, Pulmonary hypertension, Rectal haemorrhage, Stomatitis, Constipation, Diarrhoea, Nausea, Vomiting, Abdominal pain, Nasal septum perforation, Gastrointestinal perforation, Intestinal perforation, Ileus, Intestinal obstruction, Recto-vaginal fistulae, Proctalgia, Gastrointestinal ulcer, Gallbladder perforation, Wound healing complications, Exfoliative dermatitis, Dry skin, Skin discoloration, Palmar-plantar erythrodysaesthesia syndrome, Arthralgia, Myalgia, Fistula, Muscular weakness, Back pain, Osteonecrosis of the jaw, Non-mandibular osteonecrosis, Proteinuria, Ovarian failure, Pelvic Pain, Foetal abnormalities, Lethargy, Asthenia, Fatigue, Pyrexia, Pain, Mucosal inflammation.

Marketed by:

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/BEVAKALP 400 mg/16 ml, 100 mg/4 ml /APR 2025/02/ABPI
(Additional information is available on request)