

BEVAKALP

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for BEVAKALP (Bevacizumab Injection)

[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

DOSAGE AND ADMINISTRATION: As directed by physician.

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, 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, Neutropenia, Thrombocytopenia, Anaemia, Lymphopenia, Hypersensitivity, infusion reactions, Anorexia, Hypomagnesaemia, Hyponatraemia, Dehydration, Peripheral sensory neuropathic, Dysarthria, Headache, Dysgeusia, Cerebrovascular accident, Syncope, Somnolence, Posterior reversible encephalopathy syndrome, Hypertensive encephalopathy, Eye disorder, Lacrimation increased, Congestive heart failure, Supraventricular tachycardia, Hypertension, Thromboembolism (venous), Thromboembolism (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 erythrodysesthesia 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 PHARMACEUTICALS LTD.

IN/BEVAKALP 400 mg/16 ml, 100 mg/4 ml /APR-21/01/ABPI
(Additional information is available on request)