HERHOPE™

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

Abbreviated Prescribing information for **HERHOPE™** [Trastuzumab Lyophilized Powder for Concentrate for Solution for infusion] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Trastuzumab is a recombinant humanized monoclonal IgG1 antibody (containing 1328 amino acids) produced in Chinese Hamster Ovary (CHO) cell line. It is directed against an antigen called human epidermal growth factor receptor 2 (HER2).

INDICATION: Trastuzumab is indicated for the treatment of patients with HER2 overexpressing metastatic breast cancer**,** early breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma in combination with Capecitabine or 5- fluorouracil and cisplatin who have not received prior anti-cancer treatment for their metastatic disease.

DOSAGE AND ADMINISTRATION: *Loading dose:* The recommended initial loading dose is 4 mg per kg of body weight administered as a 90-minute intravenous infusion. The recommended weekly dose is 2 mg per kg of body weight. If the previous dose was well tolerated, the dose can be administered as a 30-minute infusion. First loading dose of 8 mg per kg of body weight administered as infusions over approximately 90 minutes, followed by 6 mg per kg of body weight repeated at 3 weekly intervals. Patients should be observed for fever and chills or other symptoms related to infusion. *Instructions for Reconstitution - 440 mg vial:* 1. Using a sterile syringe, slowly inject 20 ml of Sterile Bacteriostatic water into the Herhope™ 440 mg vial containing the lyophilized trastuzumab, directing the stream into the lyophilized cake. 2. Swirl vial gently to aid reconstitution. DO NOT SHAKE!

Instructions/or Reconstitution -150 mg vial:

1. Using a sterile syringe, slowly inject 7.2 mL of Sterile Bacteriostatic water into the Herhope™ 150 mg vial containing the lyophilized trastuzumab, directing the stream into the lyophilized cake.

2. Swirl vial gently to aid reconstitution. DO NOT SHAKE! Slight foaming of the product upon reconstitution is not unusual. Allow the vial to stand undisturbed for approximately 5 minutes. The reconstituted Herhope™ results in a colourless to pale yellow transparent solution and should be essentially free of visible particles.

CONTRAINDICATION: Herhope™ (Trastuzumab) is contraindicated in patients with known hypersensitivity to trastuzumab or to any other component of the drug product (Herhope™).

WARNINGS & PRECAUTIONS: Serious infusion related reactions reported infrequently to trastuzumab infusion include dyspnoea, hypotension, bronchospasm, respiratory distress, wheezing, anaphylaxis, urticaria, angioedema reduced oxygen saturation, hypertension and supraventricular tachyarrhythmia Trastuzumab should be cautiously used in pneumonitis, especially in patients being treated with taxanes concomitantly. Trastuzumab therapy is associated with increased risk of developing congestive heart failure (NYHA class II-IV) or asymptomatic cardiac dysfunction.

DRUG INTERACTIONS: There have been no formal drug interaction studies performed with trastuzumab in humans. Clinically significant interactions with the concomitant medication used in clinical trials have not been observed with respect to Trastuzumab.

ADVERSE REACTIONS: Anaemia, leukocytosis, neutropenia, thrombocytopenia, atrial fibrillation cardiac failure congestive, left ventricular dysfunction, palpitations, pericardial effusion, tachycardia, abdominal pain, aphthous stomatitis, constipation, diarrhoea, nausea, stomatitis, vomiting, asthenia, chest pain, chills, generalised oedema, pyrexia, gastroenteritis, echocardiogram abnormal, ejection fraction decreased, electrocardiogram abnormal, arthralgia, myalgia, dizziness, dysaesthesia, hypoaesthesia, neuropathy peripheral, insomnia, acute kidney injury, oliguria, dyspnoea, dyspnoea exertional, alopecia and rash pruritic.

MARKETED BY:

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(Additional information is available on request)