TRASTUNEAL™ - 150

Trastuzumab for Injection 150 mg Lyophilized Powder for Concentrate for Solution for Intravenous Infusion

Presentation: Each Trastuneal-150 Combipack contains: Vial- 1: Trastuzumab for Injection 150 mg Each vial contains: Trastuzumab (r-DNA origin) IH 150 mg, α,α - Trehalose dihydrate USP 136.2 mg, L-Histidine HCl Monohydrate EP 3.36 mg, L-Histidine USP 2.16 mg, Polysorbate 20 I.P 0.6 mg. Vial-2: Bacteriostatic Water For Injection 10ml (Diluent) Each ml contains: Benzyl Alcohol I.P 1.1% v/v, Water for Injections I.P q.s.

TRASTUNEAL™ - 440

Trastuzumab for Injection 440 mg Lyophilized Powder for Concentrate for Solution for Intravenous Infusion

Presentation: Each Trastuneal-440 Combipack contains: Vial-1: Trastuzumab for Injection 440 mg Each vial contains: Trastuzumab (r-DNA origin) IH 440 mg, α,α -Trehalose dihydrate USP 400 mg, L-Histidine HCl Monohydrate EP 9.9 mg, L-Histidine USP 6.4 mg, Polysorbate 20 I.P 1.8 mg. Vial-2: Bacteriostatic Water For Injection 20ml (Diluent) Each ml contains: Benzyl Alcohol I.P 1.1% v/v, Water for Injections I.P q.s.

Pharmaceutical form: Lyophilized Powder for concentrate for solution for Intravenous infusion.

Indications: For the treatment of patients with HER2-positive breast cancer.

Dosage and administration: Metastatic breast cancer: Three-weekly schedule: The recommended initial loading dose is 8 mg/kg body weight C maintenance is 6 mg/kg body weight, beginning three weeks after the loading dose. Weekly schedule: The recommended initial loading dose is 4 mg/kg body weight C maintenance dose of is 2 mg/kg body weight, beginning one week after the loading dose. Early breast cancer: Three-weekly and weekly schedule: The recommended initial loading dose is 8 mg/kg body weight C maintenance dose is 6 mg/kg body weight, beginning three weeks after the loading dose.

Contraindications: • Hypersensitivity to trastuzumab, murine proteins or to any of the other excipients. • Severe dyspnoea at rest due to complications of advanced malignancy or requiring supplementary oxygen therapy.

Warnings & precautions: Patients treated with Trastuzumab are at increased risk for developing CHF or asymptomatic cardiac dysfunction.

Drug interaction: Clinically significant interactions between Trastuzumab and the concomitant medicinal products used in clinical trials have not been observed.

Pregnancy & lactation: Pregnancy: Women who become pregnant should be advised of the possibility of harm to the fetus. Breastfeeding: It is not known whether trastuzumab is secreted in human milk.

Symptoms and treatment of overdosage: There is no experience with overdosage in human clinical trials. Single doses higher than 8 mg/kg have not been tested.

Storage: Store between 2°C to 8°C.

Pack size: Container closure of Trastuzumab Lyophilized powder for Injection: Glass vials (USP type-I glass) with rubber stopper and flip-off seals.

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.