SEZUMA
(Trastuzumab)

Sezuma contains the active substance trastuzumab, which is a humanized monoclonal antibody that binds to the HER-2 protein. The protein inhibits the proliferation of human tumor cells that overexpress HER-2. Sezuma contains trastuzumab as the active substance along with L-Histidine Hydrochloride Monohydrate, L-Histidine, Trehalose Dihydrate, and Polysorbate 20.

Dosage Form

Injection, powder for reconstitution.

Clinical Pharmacology – Mechanism of Action

Trastuzumab binds with high affinity and specificity to sub-domain IV, a juxta-membrane region of HER2's extracellular domain. Binding of trastuzumab to HER2 inhibits ligand-independent HER2 signaling and prevents the proteolytic cleavage of its extracellular domain, an activation mechanism of HER2. As a result, trastuzumab has been shown, in both in vitro assays and in animals, to inhibit the proliferation of human tumor cells that overexpress HER2. Additionally, trastuzumab is a potent mediator of antibody-dependent cell-mediated cytotoxicity (ADCC). In vitro, trastuzumab-mediated ADCC has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2.

Indication

Sezuma has been approved for the treatment of patients with HER-2 positive breast cancer.

Dosage and Administration

Sezuma is available in two dosages – 150 mg/single-dose vial and 440 mg/multidose vial. The route of administration of Sezuma is Intravenous (IV). Trastuzumab 150 mg and 440 mg are lyophilized powder for concentrate and solution for intravenous infusion.

Storage and Handling

Sezuma must be refrigerated at 2°C to 8°C. Protect from light.

Packaging Information

Sezuma is available as a combi-pack, which contains one vial of Trastuzumab (lyophilized powder for IV infusion) and one vial of Bacteriostatic water for injection, available in two presentations of 150mg and 440mg.

Manufactured By

M/s. Hetero Biopharma Limited,
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