

Hetero Biopharma Tocilizumab

DESCRIPTION

Tocilizumab is a recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibody of the immunoglobulin IgG1 κ (gamma 1, kappa) subclass with a typical H2L2 polypeptide structure. Each light chain and heavy chain consists of 214 and 448 amino acids, respectively. The four polypeptide chains are linked intra- and inter-molecularly by disulfide bonds. Tocilizumab has a molecular weight of approximately 148 kDa. The antibody is produced in mammalian (Chinese hamster ovary) cells.

DOSAGE FORM

Concentrate for solution for infusion (sterile concentrate). Clear to opalescent, colourless to pale yellow solution.

CLINICAL PHARMACOLOGY

Mechanism of Action

Tocilizumab binds specifically to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R). Tocilizumab has been shown to inhibit sIL-6R and mIL-6R-mediated signalling. IL-6 is a pleiotropic pro-inflammatory cytokine produced by a variety of cell types including T- and B-cells, monocytes and fibroblasts. IL-6 is involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, induction of hepatic acute phase protein synthesis and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.

INDICATION

Tocilizumab is indicated for restricted use of the drug under emergency situation in the country to treat COVID-19 hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

DOSAGE AND ADMINISTRATION

The recommended dosage for emergency use of Tocilizumab authorized under this EUA given as a single 60-minute intravenous infusion is:

If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Tocilizumab may be administered at least 8 hours after the initial infusion. Maximum Dosage in COVID-19 patients is 800 mg per infusion. Tocilizumab subcutaneous administration is not authorized for the treatment of COVID-19 patients

STORAGE & HANDLING

Tocilizumab must be refrigerated at 2°C to 8°C. Do not freeze. Protect from light by storage in the original package until time of use.

PACKAGING INFORMATION

Concentrate for solution for infusion in single use glass vials stoppered with butyl rubber stoppers packed in monocarton along with the package insert

MANUFACTURED BY

M/s. Hetero Biopharma Limited,
Survey No. 458 (Part), TSIC Formulation - SEZ,
Polepally Village, Jadcherla Mandal, Mahaboobnagar District – 509 301,
Telangana State, India.