



## **TOCILIZUMAB** (Tocilizumab)

Tocilizumab is a recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibody of the immunoglobulin IgG1 $\kappa$  (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 chain Tocilizumab has a molecular weight of approximately 148 kDa. The antibody is produced in mammalian (Chinese hamster ovary) cells.

### **Dosage Form**

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

### **Clinical Pharmacology – Mechanism of Action**

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Tocilizumab binds specifically to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL6R). 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- B-cells, monocytes, and fibroblasts. IL-6 is involved in diverse physiological processes such as T- and cell activation, induction of immunoglobulin secretion, induction of hepatic acute phase protein synthesis and stimulation of f-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**

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Tocilizumab is indicated for restricted use under emergency 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**

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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 and Handling**

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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**

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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**

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