PAMERA
(Adalimumab)

Adalimumab is produced by recombinant DNA technology in the CHO cell line and has an approximate molecularweight of 148 kilo Daltons (kDa). It is composed of two kappa light chains, each with a molecular weight of approximately 24 kDa, and two heavy chains, each with a molecular weight of approximately 49 kDa. The total molecular weight of adalimumab is 148 kDa. Each light chain consists of 214 amino acid residues, and each heavy chain consists of 451 amino acid residues. Thus, the total amino acid content for Adalimumab is 1330. One N-linked glycosylation site is located at Asn301 on each heavy chain. Adalimumab is specific for human tumor necrosis factor (TNF-alpha).

Dosage Form

Solution for injection.

Clinical Pharmacology – Mechanism of Action

Adalimumab is a recombinant human immunoglobulin (IgG1) monoclonal antibody containing human peptide sequences that binds to human TNF-alpha and neutralizes the biological functions of TNF-alpha by blocking its interaction with the p55 and p75 cell surface TNF-alpha receptors, thus preventing inflammation.

Indication

Adalimumab is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs, including methotrexate, has been inadequate. It is also indicated for the treatment of severe, active, and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Adalimumab is indicated for the treatment of Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), Axial Spondyloarthritis (AS), Psoriatic Arthritis (PsA), Psoriasis, Pediatric Plaque Psoriasis, Hidradenitis Suppurativea (HS), Crohn's disease, Pediatric Crohn's disease, Ulcerative colitis, and Uveitis.

Dosage and Administration

Adalimumab injection: 40 mg/0.8 mL

Storage and Handling

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled syringe or pre-filled pen in its outer carton to protect it from light.

Packaging Information

Adalimumab drug product of different strengths is filled in pre-sterilized glass syringes of 1 ml capacity, which is with a fixed stainless steel needle and needle shield (make: BD, USA). Upon filling of the drug product into the pre-filled syringe, the syringe is stoppered with a pre-sterilized elastomeric butyl rubber stopper. Then, the plunger rod is inserted. The complete pre-filled syringe is placed into the plastic tray, which holds the syringe intact at all times, and the tray is placed into the carton box, which acts as a secondary packaging system.

Manufactured By

M/s. Hetero Biopharma Limited,
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