ADFRAR P

For the use of rheumatologists, gastroenterologists, orthopaedicians, dermatologists, clinical immunologists and internal physicians and pediatricians experienced in the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and plaque psoriasis patients only

Abbreviated Prescribing information for **ADFRAR P** [Adalimumab Injection 40mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Adalimumab is a fully human monoclonal antibody of the IgG1 iso type that neutralizes the biological function of TNF-α by blocking its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab decreases the levels of acute phase reactants of inflammation (C-reactive protein [CRP] and erythrocyte sedimentation rate [ESR]) in patients with rheumatoid arthritis. **INDICATION**: Indicated in the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankyloslng spondylitis, crohn's disease, ulcerative colitis, plaque psoriasis. **DOSAGE AND ADMINISTRATION**: It is administered by subcutaneous injection. For treatment of rheumatoid arthritis, psoriatic arthritis and ankyloslng spondylitis recommended adult dose is 40mg every other week. For treatment of juvenile idiopathic arthritis dosage should be vary from 10-40mg every other week depending upon age. For treatment of crohn's disease dosage should be vary from 20-160mg every other week depending upon age group and for treatment of plaque psoriasis dose should be from 40-80mg every other week. **CONTRAINDICATION:** Contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, or severe hepatic impairment, and in patients who are hypersensitive to any component of this product. **WARNINGS & PRECAUTIONS**: Use cautiously or stop adalimumab if patient develops a serious infection or sepsis, lymphoma, other malignancies. Monitor patients with heart failure carefully during the treatment. **DRUG INTERACTIONS**: It may interact with drugs like abatacept, tocilizumab, anakinra, methotrexate, rituximab and live vaccines. **ADVERSE REACTIONS**: Injection site reactions, infusion reactions with infliximab, human antichimeric antibodies (HACA), human antihuman antibodies (HAHA), the risk of rare serious infections, pancytopenia and elevated transamines, congestive heart failure, a lupus-like syndrome, a promotion of lymphoma, anaemia, leukocytosis, pancytopenia, myocardial infarction, tachycardia, vertigo, dry eye, gastritis, lip ulceration, reflux gastritis, stomatitis, pyrexia, acute sinusitis, appendicitis, herpes zoster, pulmonary tuberculosis, tuberculosis, urinary tract infection, alanine aminotransferase increased, transaminases increased, diabetes mellitus, vitamin d deficiency, neck pain, nephrolithiasis, urticaria and multiple sclerosis/neurological disease.

MARKETED BY:

torrent PHARMA

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IN/ADFRAR P 40 mg/0.8 ml /FEB-2016/01/ABPI
(Additional information is available on request)