ADFRAR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ADFRAR [Adalimumab Injection 40 mg/0.4 ml and 20 mg/0.2 ml (r-DNA origin) in pre-filled syringe]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Adalimumab is a fully human monoclonal antibody of the IgG1 isotype that neutralizes the biological function of TNF-α by blocking its interaction with the p55 and p75 cell surface TNF receptors.

INDICATIONS: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, and Plaque psoriasis

DOSAGE AND ADMINISTRATION: Adfrar (adalimumab) is administered by subcutaneous injection. *Rheumatoid arthritis, Ankylosing Spondylitis, psoriatic arthritis:* For adults, 40 mg subcutaneously every other week. *Usual Pediatric Dose for Juvenile Idiopathic Arthritis:* 10 kg to < 15 kg 10 mg every other week, 15 kg to < 30 kg 20 mg every other week, and > 30 kg 40 mg every other week. *Usual adult Dose for Crohn's Disease:* 160 mg subcutaneously on Day 1, Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week. *Usual Pediatric Dose for Crohn's Disease (6 years of age and older)* 17 kg to < 40 kg 80 mg on Day 1 (administered as two 40 mg injections in one day); and 40 mg two week later (on Day 15). > 40 kg 160 mg on Day 1 (administered as four injections per day for two consecutive day); and 80 mg two weeks later (on Day 15) (administered as two 40mg injections in one day). *Usual Adult Dose for Ulcerative Colitis:* Initial dose: 160 mg subcutaneously on Day 1, Maintenance dose: Two weeks later (Day 29). *Plaque psoriasis:* Initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

CONTRAINDICATION: Adfrar (adalimumab) should not be administered to patients with known hypersensitivity to adalimumab or any of its components. Adfrar (adalimumab) also is contraindicated in patients with active tuberculosis or other severe infections (such as sepsis and opportunistic infections) and moderate to severe heart failure (NYHA class III/IV).

WARNINGS & PRECAUTIONS: *Serious infection:* As per reports in literature, patients on TNF alpha blockers such as infliximab and adalimumab are at an increased risk of developing serious infections. Discontinue Adfrar (adalimumab) if a patient develops a serious infection or sepsis. Reported infections include active TB (including reactivation of latent TB), invasive fungal infections (including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, and pneumocystosis), and bacterial, viral, or other infections caused by opportunistic pathogens. *Malignancy:* Lymphoma and other malignancies, some fatal, have been reported in children and adolescents treated with TNF blockers, including adalimumab. Post marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including adalimumab. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases has occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. *Non-melanoma skin cancer (NMSC):* The rate (95% confidence interval) of NMSC was 0.8 (0.52, 1.11) per 100 patient-years among innovator product-treated patients and 0.3 (0.11, 0.63) per 100 patient-years among controltreated patients. *Lymphoma and Leukemia:* In the controlled portions of clinical trials of all the TNF-blockers in adults, more cases of lymphoma have been observed among TNF-blocker-treated patients compared to controltreated patients. *Hypersensitivity:* Anaphylaxis and angioedema have been rarely reported. *Autoimmunity:* May result in formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. *Heart failure:* Worsening of chronic heart failure (CHF) and new-onset CHF have occurred. *Hepatitis B:* Risk of reactivation of hepatitis B virus (HBV) may be increased in chronic carriers of this virus. *Neurologic events:* Rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease, including multiple sclerosis, and peripheral demyelinating disease, including Guillain- Barré syndrome, have occurred.

DRUG INTERACTIONS: Abatacept, tocilizumab: An increased rate of infection may occur. Concurrent therapy is not recommended. If co-administration occurs, closely monitor for signs of infection. Anakinra: Do not use in combination; increased risk of serious infections and neutropenia. Live vaccines: Do not give concurrently. Methotrexate: Reduces apparent clearance of Adfrar (adalimumab); however, adjustments in the dose of either

drug do not appear necessary. Rituximab: A higher rate of serious infection has been observed in patients with RA treated with rituximab and subsequently receiving a TNF blocker (e.g. adalimumab). There is insufficient information to provide recommendations for concurrent use of Adfrar (adalimumab) and other biologic products.

ADVERSE REACTIONS: Although TNF blockers are generally well tolerated, the existence of any drawbacks to the use of these agents needs to be considered before the commencement of therapy. TNF-antagonist therapy is commonly associated with induction of auto antibodies, including anti-dsDNA antibodies; however, anti-TNF-induced lupus is not very common. Renal, cerebral and cutaneous involvement may occur more frequently than the classical drug-induced lupus. The most common side effects of these therapies are injection site reactions to subcutaneously administered drugs (local erythema and swelling usually subside within 24 h, and can be lessened by antihistaminics), or infusion reactions with infliximab; it is not necessary to stop the treatment and these side effects do not interfere with the efficacy of the drugs. Development of antibodies against the drug – human antichimeric antibodies (HACA; infliximab) or human antihuman antibodies (HAHA; etanercept/adalimumab) – is a problem for TNF therapies. In general, the most common side effects of Adalimumab are injection site reactions. Adalimumab increases the risk of rare serious infections. There is a two-fold risk of serious infections with the use of adalimumab. It should not be used during periods of active infection. Its most notable infectious complication is the reactivation of tuberculosis. Deep fungal and other serious and atypical infection can also be promoted by adalimumab. It has been associated infrequently with skin rashes. Rare side effects include: worsening or initiation of congestive heart failure, a lupus-like syndrome, a promotion of lymphoma, medically significant cytopenias, and worsening or initiation of a multiple sclerosis/neurological disease. There has been reported pancytopenia and elevated transamines with the use of adalimumab, which suggest that laboratory monitoring blood counts and liver functions, at least intermittently, is useful. Anaemia, Leukocytosis, Pancytopenia, Myocardial infarction, Tachycardia, Vertigo, Dry eye, Gastritis, Lip ulceration, Reflux gastritis, Stomatitis, Injection site reaction, Local swelling, Pyrexia, Acute sinusitis, Appendicitis, Cellulitis, Dengue fever, Erythema induratum, Gastroenteritis, Herpes zoster, Neutropenic sepsis, Pulmonary tuberculosis, Respiratory tract infection, Tuberculosis, Upper respiratory tract infection, Urinary tract infection, Alanine aminotransferase increased, Transaminases increased, Diabetes mellitus, Dyslipidaemia, Hyperuricaemia, Vitamin D deficiency, Neck pain, Anxiety, Depression, Nephrolithiasis, Urate nephropathy, Cough, Dyspnoea, Skin mass, and Urticaria.

MARKETED BY:

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/ADFRAR 100 mg/mL/AUG-2025/01/ABPI

(Additional information is available on request)