Fenograf

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

Abbreviated prescribing information for Fenograf (Mycophenolate Mofetil 500 mg and 750 mg Tablets). [Please refer the complete prescribing information for details available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Mycophenolate mofetil is the 2-morpholinoethyl ester of mycophenolic acid (MPA), an immunosuppressive agent; inosine monophosphate dehydrogenase (IMPDH) inhibitor. **INDICATION:** For the prophylaxis of acute organ rejection in patients receiving allorgenic hepatic transplantation. **DOSAGE AND ADMINISTRATION:** ***Renal Transplantation:*** *Adults:* A dose of 1 g administered orally twice a day (daily dose of 2 g) is recommended for use in renal transplant patients. *Pediatrics (3 months to 18 years of age):* Patients with a body surface area >1.5 m^2 may be dosed with Mycophenolate Mofetil tablet at a dose of 1 g twice daily (2 g daily dose). ***Cardiac Transplantation:*** A dose of 1.5 g bid administered oral (daily dose of 3 g) is recommended for use in adult cardiac transplant patients. ***Hepatic Transplantation:*** A dose of 1.5 g bid oral (daily dose of 3 g) is recommended for use in adult hepatic transplant patients. ***Geriatrics:*** The recommended oral dose of 1 g bid for renal transplant patients, 1.5 g bid for cardiac transplant patients, and 1.5 g bid administered orally in hepatic transplant patients is appropriate for elderly patients. **CONTRAINDICATION:** Mycophenolate Mofetil is contraindicated in patients with hypersensitivity to mycophenolate Mofetil, mycophenolic acid or to any component of the drug product. **WARNINGS & PRECAUTIONS:** MPA increased risk of embryofetal toxicity, lymphoma and malignancy, serious infections, new or reactivated viral infections, neutropenia pure red cell aplasia (PRCA), gastrointestinal disorders and infections in cardiac transplant patients. Precaution should be taken with pregnancy exposure prevention and planning, pregnancy testing, contraception, in patients with renal impairment, in patients with HGPRT deficiency, on immunizations and with laboratory tests. **DRUG INTERACTION:** Acyclovir, Antacids with Magnesium and Aluminum Hydroxides, Proton Pump Inhibitors (PPIs), Cholestyramine, Cyclosporine, Ganciclovir, Oral Contraceptives, Sevelamer, Trimethoprim/sulfamethoxazole, Norfloxacin and Metronidazole, Ciprofloxacin and Amoxicillin plus Clavulanic Acid, Rifampin, Drugs that alter the gastrointestinal flora may interact with mycophenolate mofetil by disrupting enterohepatic recirculation and Live Vaccines. **ADVERSE REACTIONS:** Diarrhea, leukopenia, sepsis, vomiting, certain types of infections, pain, abdominal pain, fever, Headache, Asthenia, Chest pain, back pain, Ascites, Anemia, Leukopenia, Thrombocytopenia, Hypochromic anemia, Leukocytosis, Urinary tract infection, Kidney function abnormal, hypotension, hypertension, cardiovascular disorder, tachycardia, Peripheral edema, Hyper-cholesteremia, Edema, lab test abnormal, Constipation, Nausea, Dyspepsia, Anorexia, Liver function tests abnormal, Dyspnea, Cough increased, Lung disorder, Sinusitis, Pleural effusion, Rash, Tremor, Insomnia, Dizziness, Anxiety, Paresthesia and other reactions mentioned in warning and precaution section.

MARKETED BY

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(Additional information is available on request)