FENOGRAF S

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

Abbreviated Prescribing information for Fenograf S (Mycophenolate Sodium 360 mg Delayed Release Tablets U.S.P.).

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Mycophenolate mofetil is the 2-morpholinoethyl ester of MPA. MPA is a potent, selective, uncompetitive and reversible inhibitor of inosine monophosphate dehydrogenase, and therefore inhibits the *de novo* pathway of guanosine nucleotide synthesis without incorporation into DNA. Because T- and B-lymphocytes are critically dependent for their proliferation on *de novo* synthesis of purines whereas other cell types can utilise salvage pathways, MPA has more potent cytostatic effects on lymphocytes than on other cells.

DOSAGE AND ADMINISTRATION: *Dosage in Adult Kidney Transplant Patients:* The recommended dose of Mycophenolate Sodium is 720 mg administered twice daily (1440 mg total daily dose). *Dosage in Pediatric Kidney Transplant Patients:* The recommended dose of Mycophenolate Sodium in conversion (at least 6 months post-transplant) pediatric patients age 5 years and older is 400 mg/m body surface area (BSA) administered twice daily (up to a maximum dose of 720 mg administered twice daily).

CONTRAINDICATION: Mycophenolate Sodium is contraindicated in patients with a hypersensitivity to mycophenolate sodium, mycophenolic acid, mycophenolate mofetil, or to any of its excipients. Reactions like rash, pruritus, hypotension, and chest pain have been reported in clinical trials and post marketing reports.

WARNINGS & PRECAUTIONS: Use of MPA increased risk of embryofetal Toxicity, lymphoma and other malignancies, serious infections, new or reactivated viral infections, blood dyscrasias including pure red cell aplasia and serious GI Tract complications. Precautions should be taken for pregnancy exposure prevention and planning, on management of immunosuppression, during immunizations and in patients of rare hereditary deficiencies.

DRUG INTERACTION: Antacids with Magnesium and Aluminum Hydroxides, Azathioprine, Cholestyramine, Bile Acid Sequestrates, Oral Activated Charcoal and Other Drugs that Interfere with Enterohepatic Recirculation, Sevelamer, Cyclosporine, Norfloxacin and Metronidazole, Rifampin, Hormonal Contraceptives, Acyclovir (Valacyclovir), Ganciclovir (Valganciclovir), and Other Drugs that Undergo Renal

Tubular Secretion, Ciprofloxacin, Amoxicillin plus Clavulanic Acid and Other Drugs that Alter the Gastrointestinal Flora and Pantoprazole.

ADVERSE REACTIONS: Anemia, leukopenia, constipation, nausea, diarrhea, vomiting, dyspepcia, abdominal pain upper, flatulence, edema, pyrexia, hypocalcemia, hyperlipidemia, hyperuricemia, hypokalemia, hypophosphatemia, back pain, arthralgia, tremor, insomnia, headache, hypertension, viral, fungal and bacterial infections, intestinal perforation, gastrointestinal hemorrhage, gastric ulcers, duodenal ulcers, colitis (including CMV colitis), pancreatitis, esophagitis, ileus, interstitial lung disorders, including fatal pulmonary fibrosis and reaction mentioned in warning and precaution section.

MARKETED BY

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(Additional information is available on request)