FENOGRAF 500

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

Abbreviated Prescribing information for FENOGRAF 500 (Mycophenolate mofetil Tablets I.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: Use in renal transplant: *Adults* Oral FENOGRAF 500 should be initiated within 72 hours following transplantation. The recommended dose in renal transplant patients is 1 g administered twice daily (2 g daily dose) *Paediatric population* aged 2 to 18 year, The recommended dose of mycophenolate mofetil is 600 mg/m2 administered orally twice daily (up to a maximum of 2 g daily). *Paediatric population* < 2 years**. Use in cardiac transplant:** *Adults* Oral FENOGRAF 500 should be initiated within 5 days following transplantation. The recommended dose in cardiac transplant patients is 1.5 g administered twice daily (3 g daily dose). **Use in hepatic transplant:** *Adults* Intravenous mycophenolate mofetil should be administered for the first 4 days following hepatic transplant, with oral FENOGRAF 500 initiated as soon after this as it can be tolerated.

CONTRAINDICATION: FENOGRAF 500 should not be given to patients with hypersensitivity to mycophenolate mofetil, mycophenolic acid or to any of the excipients. Hypersensitivity reactions to FENOGRAF 500 have been observed, It should not be given to women of childbearing potential who are not using highly effective contraception, FENOGRAF 500 treatment should not be initiated in women of childbearing potential without providing a pregnancy test result to rule out unintended use in pregnancy, FENOGRAF 500 should not be used during pregnancy unless there is no suitable alternative treatment to prevent transplant rejection, FENOGRAF 500 should not be given to women who are breastfeeding.

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)