FENOGRAF 250

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

Abbreviated Prescribing information for Fenograf 250 (Mycophenolate mofetil capsules 250 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Mycophenolate mofetil is an immunosuppressive agent. Mycophenolate mofetil is the 2-morpholinoethyl ester of mycophenolic acid (MPA). MPA is a potent, selective, uncompetitive and reversible inhibitor of inosine monophosphate dehydrogenase.

INDICATIONS: For the prophylaxis of acute organ rejection in patients receiving allogenic hepatic transplantation.

DOSAGE AND ADMINISTRATION: Use in renal transplant: The recommended dose is 1 g administered twice daily. Children and adolescents (aged 2 to 18 years): the recommended dose of is 600 mg/m^2 administered orally twice daily (up to a maximum of 2 g daily). Children (< 2 years): there are limited safety and efficacy. These are insufficient to make dosage recommendations and therefore use in this age group is not recommended. Use in cardiac transplant: Adults: The recommended dose is 1.5 g administered twice daily (3 g daily dose). Use in hepatic transplant: Adults: The recommended oral dose is 1.5 g administered twice daily (3 g daily dose). Use in elderly (≥ 65 years): the recommended dose of 1 g administered twice a day for renal transplant patients and1.5 g twice a day for cardiac or hepatic transplant patients is appropriate for the elderly. Use in renal impairment: doses greater than 1 g administered twice a day should be avoided.

CONTRAINDICATION: In patients with a hypersensitivity to mycophenolate mofetil or mycophenolic acid and in women who are breastfeeding.

WARNINGS & PRECAUTIONS: Patients receiving mycophenolate mofetil are at increased risk of developing lymphomas and other malignancies, particularly of the skin and also opportunistic infections (bacterial, fungal, viral and protozoal), fatal infections and sepsis. Cases of hepatitis, bronchiectasis, pure red cell aplasia (PRCA) and hypogammaglobulinaemia have been reported. There have also been isolated reports of interstitial lung disease and pulmonary fibrosis, some of which were fatal. Patients receiving mycophenolate mofetil should be monitored for neutropenia. Patients should be advised that during treatment with mycophenolate mofetil, vaccinations may be less effective and the use of live attenuated vaccines should be avoided. Because mycophenolate mofetil has been associated with an increased incidence of digestive system adverse events, including infrequent cases of gastrointestinal tract ulceration, haemorrhage and perforation, it should be avoided in patients with Lesch-Nyhan and Kelley- Seegmiller syndrome. It is recommended that mycophenolate mofetil should not be administered concomitantly with azathioprine and drugs that interfere with enterohepatic recirculation.

DRUG INTERACTIONS: Aciclovir, antacids and proton pump inhibitors (PPIs), cholestyramine, cyclosporine A, ganciclovir, rifampicin, sevelamer, norfloxacin, metronidazole, ciprofloxacin, amoxicillin plus clavulanic acid and tacrolimus.

ADVERSE REACTIONS: Gastrointestinal candidiasis, urinary tract infection, herpes simplex, herpes zoster, leucopenia, renal impairment ,arthralgia, thrombocytopenia, pneumonia, influenza, anaemia, vomiting, acidosis, hyperkalaemia, abdominal pain, diarrhoea, nausea, gingival hyperplasia, cytomegalovirus colitis, pancreatitis, intestinal villous atrophy, meningitis, endocarditis, tuberculosis, atypical mycobacterial infection, BK virus associated nephropathy, progressive multifocal leucoencephalopathy, aplastic anaemia, bone marrow depression, acquired Pelger-Huetanomaly, angioneurotic oedema, anaphylactic reaction, interstitial lung disease, and pulmonary fibrosis.

MARKETED BY:

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(Additional information is available on request)