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Mycolate™

(Mycophenolate Mofetil)

Tablet

مائیکولیٹ

COMPOSITION:
Each film coated tablet contains:
Mycophenolate Mofetil ..... 500 mg.

Product Specs.: USP

DRUG DESCRIPTION:
Mycophenolic acid Mycophenolate is an immunosuppressant drug used to prevent rejection in organ transplantation.
Pharmacodynamics:
Mycophenolic acid acts by blocking purine synthesis of human lymphocytes through reversible inhibition of inosine monophosphate dehydrogenase. It also inhibits proliferation of both T- and B- lymphocytes.

PHARMACOKINETICS:
Absorption: Mycophenolate mofetil is extensively absorbed from the GI tract.
Distribution: Mycophenolic acid (MPA): 97% bound to plasma proteins.
Metabolism: Mycophenolate is converted to active MPA (Mycophenolic acid), which undergoes enterohepatic recirculation. MPA is metabolised by glucuronidation to the inactive glucuronide.
Excretion: Via urine (as the glucuronide and negligible amounts of MPA); via faeces (about 6% of a dose). Mean half-life of MPA: 17.9 hours (as oral Mycophenolate mofetil) and 16.6 hours (as IV Mycophenolate mofetil); 12 hours (as Mycophenolate sodium).
Special Populations:
Pregnancy:
Contraindicated in pregnancy
Category C: Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus.
Lactation: Contraindicated in lactation
Children: Safety and efficacy in cardiac or hepatic transplants not established.
Geriatic: Use with caution because of the greater frequency of decreased hepatic, renal, or cardiac function, and concomitant diseases or other drug therapy.

INDICATIONS:
Mycolate is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. Mycolate should be used concomitantly with cyclosporine and corticosteroids.

ADVERSE REACTIONS:
Diarrhoea, vomiting, GI haemorrhage and perforation; leukopenia; asthenia, pain, headache, anaemia, thrombocytopenia, renal tubular necrosis, haematuria, BP changes, hyperglycaemia, disturbances of electrolytes and blood lipids, peripheral oedema, dyspnoea, cough, acne, rash, alopecia, dizziness, insomnia, paraesthesia, tremor, hypersensitivity reactions, pancreatitis, hepatitis.
Potentially fatal:
Angioedema, anaphylaxis, fatal pulmonary fibrosis.

PRECAUTIONS AND WARNINGS:
Administer under the supervision of a health care provider experienced in immunosuppressive therapy and management of organ transplantation and in an equipped facility. Increased risk of lymphoma and increased susceptibility to infection may be related to immunosuppression. Administration is associated with increased risk of pregnancy loss and congenital malformations. Women of childbearing potential must use contraception.
Special precautions:
Teratogenic in animals; avoid inhalation or direct skin contact. Monitor patients for lymphoproliferative disorders; advise patient to limit exposure to sunlight/UV light. Active peptic ulcer disease. Severe renal impairment. Mycophenolate mofetil and Mycophenolate sodium are not interchangeable. Perform CBCs; monitor for neutropenia.
Monitor. Perform CBCs weekly during the first month, twice monthly during the second and third months, then monthly through the first year. Monitor patient for signs and symptoms of bacterial, viral, or fungal infections, and for signs and symptoms of organ rejection.

OVERDOSAGE:
No reported cases. At plasma levels >100 mcg/ml, small amounts of the inactive metabolite may be removed by haemodialysis. Excretion of MPA may be enhanced by bile acid sequestrants (e.g. colestyramine).

DRUG INTERACTIONS:
Increased plasma levels of Mycophenolate drug when combined with aciclovir, valaciclovir, ganciclovir and valganciclovir. Reduced absorption with colestyramine, magnesium- and aluminium hydroxide-containing products, sevelamer and other calcium-free phosphate binders. Reduced plasma levels with ciclosporin, metronidazole, quinolones, rifamycins. May reduce plasma levels of progestins; may reduce efficacy of oral contraceptives. Increased plasma levels with probenecid. May reduce efficacy of live vaccines.

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OTHER INTERACTIONS:
Food interaction:
Food reduces MPA peak serum levels by 40% following Mycophenolate mofetil administration. Extent of absorption is not affected. Avoid cat's claw and echinacea as they have immunostimulant effects.

DOSAGE:
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. Although a dose of 1.5 g administered twice daily (daily dose of 3 g) was used in clinical trials and was shown to be safe and effective, no efficacy advantage could be established for renal transplant patients. Patients receiving 2 g/day of Mycophenolate mofetil demonstrated an overall better safety profile than did patients receiving 3 g/day of Mycophenolate mofetil.
Cardiac transplantation:
Adults:
A dose of 1.5 g bid oral (daily dose of 3 g) is recommended for use in adult cardiac transplant patients.
Hepatic transplantation:
Adults:
A dose of 1.5 g bid oral (daily dose of 3 g) is recommended for use in adult hepatic transplant patients.
Mycophenolate mofetil with food:
The initial oral dose of Mycophenolate mofetil should be given as soon as possible following renal, cardiac or hepatic transplantation. Food had no effect on MPA AUC, but has been shown to decrease MPA Cmax by 40%. Therefore, it is recommended that Mycophenolate mofetil be administered on an empty stomach. However, in stable renal transplant patients, Mycophenolate mofetil may be administered with food if necessary.
Patients with Hepatic Impairment:
No dose adjustments are recommended for renal patients with severe hepatic parenchymal: disease. However, it is not known whether dose adjustments are needed for hepatic disease with other etiologies.
No data are available for cardiac transplant patients with severe hepatic parenchymal disease.
Geriatrics:
The recommended oral dose of 1 g bid for renal transplant patients, 1.5 g bid for cardiac transplant patients, 1.5 g bid administered orally in hepatic transplant patients is appropriate for elderly patients.

CONTRAINDICATIONS:
Pregnancy, lactation. Rare hereditary deficiency of hypoxanthine-guanine phosphoribosyltransferase (HGPRT), including Kelley-Seegmiller or Lesch-Nyhan syndrome.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Mycolate Tablet 500 mg : Pack of 5x10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

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