NOVARTIS

MYFORTIC®

(mycophenolic acid as mycophenolate sodium)

180 mg and 360 mg gastro-resistant tablets

Basic Succinct Statement

Code: BSS RD 30 OCT 13; APPR 16 MAR 17

This material is only meant for Healthcare Professionals

MYFORTIC® 180 mg and 360 mg Gastro-resistant Tablets

Importante note: Before prescribing, consult full prescribing information.

Presentation: Mycophenolic acid (as mycophenolate sodium). Gastro-resistant tablet containing 180 mg or 360 mg of mycophenolic acid (as mycophenolate sodium).

Indications: Prophylaxis of acute transplant rejection in patients receiving allogeneic renal transplants in combination with ciclosporin for microemulsion and corticosteroids.

Dosage: ♦Recommended dose is 720 mg administered twice daily (1,440 mg daily dose). ♦Patients with severe chronic renal impairment (glomerular filtration rate $< 25\ mL \cdot min^{-1} \cdot 1.73\ m^{-2}$), should be carefully followed up. ♦Very limited experience in children.

Contraindications: ♦Hypersensitivity to mycophenolate sodium, mycophenolic acid or mycophenolate mofetil or to any of the excipients. ♦Women of child bearing potential (WOCBP) who are not using highly effective contraception methods. ♦Should not be initiated in women of child bearing potential without providing a pregnancy test result to rule out unintended use in pregnancy. ♦Pregnancy unless there is no suitable alternative treatment to prevent transplant rejection. ♦Women who are breastfeeding.

Warnings/Precautions: ♦ Mycophenolate is a powerful human teratogen. ♦Increased risk of developing lymphomas and other malignancies, particularly of the skin. ♦Over-suppression of the immune system with increased susceptibility to infection. ♦Viral reactivation reported in patients infected with HBV or HCV: Monitoring patients infected with hepatitis B or C for clinical and laboratory signs of active HBV or HCV infection recommended. ♦Cases of progressive multifocal leukoencephalopathy and pure red cell aplasia have been reported in patients treated with mycophenolate mofetil. Patients with active serious digestive system disease should be treated with caution. ♦Patients with hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) should not use Myfortic®. ♦Patients should be instructed to report any sign of bone marrow depression. ♦Complete blood counts should be performed on a regular basis for monitoring neutropenia. ♦Increased risk of congenital malformations if used during pregnancy. ♦Women of childbearing age must use highly effective contraception. ♦Myfortic therapy should not be initiated until a negative pregnancy test has been obtained. ♦Myfortic increases risk of pregnancy loss including spontaneous abortion. ♦Myfortic should not be used during pregnancy unless clearly necessary. ♦Male patients under treatment should use condoms and their partner should use highly effective contraception. ♦Myfortic should not be used by breast-feeding mothers ♦Use of live attenuated vaccines should be avoided.

Interactions: ♦Live vaccines should not be given. ♦Caution with concomitant use of cholestyramine and drugs that interfere with enterohepatic circulation. ♦Caution with concomitant use of aciclovir, ganciclovir and oral contraceptives. ♦Caution with concomitant use of antacids containing magnesium and aluminium hydroxides. In a PK study no interaction was demonstrated with pantoprazole use ♦Azathioprine should not be used since concomitant administration with Myfortic has not been studied. ♦Systemic concentration of Myfortic may change when switching from ciclosporin to tacrolimus and vice versa.

Adverse reactions: ♦Adverse drug reactions associated with the administration of Myfortic in combination with ciclosporin for microemulsion and corticosteroids include: ♦**Very common:** viral, bacterial and fungal infections, leucopenia, hypocalcemia, hypokalemia, hyperuricemia, hypertension, hypotension, diarrhea. ♦**Common**: upper respiratory tract infections, pneumonia, anemia, thrombocytopenia, hyperkalemia, hypomagnesemia, anxiety, dizziness, headache, , aggravated hypertension, cough, dyspnoea, dyspnea exertional, hepatic function tests abnormal, abdominal distension, abdominal pain, constipation, dyspepsia, flatulence, gastritis, loose stools, nausea, vomiting, arthralgia, asthenia, myalgia, increased blood creatinine, fatigue, edema peripheral, pyrexia. ♦**Uncommon**: wound infection, sepsis, osteomyelitis, lymphocele, lymphopenia, neutropenia, lymphadenopathy, anorexia, hyperlipidemia, diabetes mellitus, hypercholesterolemia, hypophosphatemia, delusional perception, tremor, insomnia, conjunctivitis, vision blurred, acne, tachycardia, pulmonary edema, interstitial lung disease including fatal pulmonary fibrosis, pulmonary congestion, wheezing, abdominal tenderness, pancreatitis, eructation, halitosis, ileus, esophagitis, peptic ulcer, subileus, gastrointestinal hemorrhage, dry mouth, lip ulceration, parotid duct obstruction, gastro-esophageal reflux disease, gingival hyperplasia, peritonitis, alopecia, contusion, back pain, muscle cramps, hematuria, renal tubular necrosis, urethral stricture, influenza-like illness, oedema lower limb, pain, rigors, weakness. ♦**Frequency unknown:** Rash ♦**The following adverse reactions are attributed to mycophenolic acid derivatives as class effect**: Agranulocytosis, colitis, esophagitis, gastritis, pancreatitis, intestinal perforation, gastrointestinal hemorrhage, gastric ulcers, duodenal ulcers, ileus, serious infections, polyomavirus (especially BK virus) associated nephropathy, neutropenia, pancytopenia. Cases of progressive multifocal leukoencephalopathy and pure red cell aplasia have been reported. Cases of spontaneous abortion have been reported in patients exposed to mycophenolate mainly in the first trimester. Congenital malformations have been observed post-marketing in children of patients exposed to mycophenolate in combination with other immunosuppressants