ACR/ARP Medication Guide



ASSOCIATION of **RHEUMATOLOGY PROFESSIONALS** The Interprofessional Division of the American College of Rheumatology

Mycophenolate (Cellcept, Myfortic)

Note: Mycophenolate mofetil (CellCept) and mycophenolate sodium (Myfortic) are NOT equivalent

Mycophenolate exhibits cytostatic and reversible effect on T and B lymphocytes byt inhibiting type I and II inosine monophosphate dehydrogenase (IMPDH) which inhibits nucleotide synthesis and blocks DNA synthesis, causing T cells to become less responsive to antigenic stimulation. T and B lymphocytes are dependent on this pathway for proliferation. It also prevents intercellular adhesion to endothelial cells which can inhibit leukocytes into sites of inflammation and graft rejection.

Resources from Manufacturer

<u>CellCept Package Insert</u> <u>CellCept Patient Medication Guide</u> <u>CellCept Copay Card</u> <u>Myfortic Package Insert</u> <u>Myfortic Patient Medication Guide</u> <u>Myfortic Copay Card</u>

Indications and Dosing in Rheumatology

*FDA approved indications

Adults

- *Organ Transplantation: dependent on organ transplanted
- Dermatomyositis (cutaneous), refractory: mycophenolate mofetil: 500mg by mouth twice daily for two weeks, then 1g twice daily
- Eosinophilic granulomatosis with polyangiitis: mycophenolate mofetil: 750mg-1.5g by mouth twice daily
- Focal segmental glomerulosclerosis, glocu-corticoid dependent or glucocorticoid resistant: mycophenolate mofetil: 750mg – 1g twice daily with low-dose glucocorticoids; mycophenolate sodium: 540-720mg by mouth twice daily with low-dose glucocorticoids
- Lupus erythematosus, discoid lupus and subacute cutaneous lupus: mycophenolate mofetil: 1 to 1.5g by mouth twice daily; mycophenolate sodium: 720mg by mouth twice daily for duration of 2-3 months
- Lupus nephritis, focal or diffuse: mycophenolate mofetil: 1 to 1.5g by mouth twice daily duration typically 2 years; mycophenolate sodium: 720mg by mouth twice daily
- Takayasu arteritis: mycophenolate mofetil: 750-1.5g by mouth twice daily as tolerated with combination glucocorticoids

Pediatrics

Lupus Nephritis: mycophenolate mofetil: 300-600 mg/m2 twice daily, maximum 3g/day

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Contraindications

Hypersensitivity to mycophenolate mofetil, mycophenolic acid, mycophenolate sodium, or any component of the formulation.

Mycophenolate mofetil (CellCept): IV formulation is also contraindicated in patients who are allergic to polysorbate 80 (Tween).

Warnings and Precautions

- New or reactivated viral infections: consider reducing dose
- Blood dsycrasias: monitor for neutropenia or anemia
- May cause CNS depression which may impair physical or mental abilities
- Use in caution in patient with active serious digestive system disease
- Use with cautions in patients with renal impairment
- Immunizations: avoid live vaccinations
- Patients with hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT): may cause exacerbation of disease
- Blood donation should be avoided during therapy for 6 weeks thereafter
- Semen donation should be avoided during therapy and for 90 days thereafter
- Some dosage forms may contain phenylalanine and polysorbate 80, use caution in patients with hypersensitivity
- Use during pregnancy is associated with first trimester loss and congenital malformations
- Increased risk of development of lymphoma and other malignancies
- Increase susceptibility to infection, including opportunistic infections

Adverse Reactions

Most common adverse reactions (>20%): anemia, leukopenia, constipation, nausea, diarrhea, committing, dyspepsia, infections and insomnia.

Medication Strength and Preparations

- Available as mycophenolate mofetil: 250mg capsules, 500mg tablets, 500mg IV solution, 200mg/mL suspension
- Available as mycophenolate sodium delayed release: 180mg and 360mg tablets

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Medication Administration and Storage

Oral

- Capsules/tablets: stored at room temperature, protect from light
- Oral suspension: once reconstituted can be stored at room temperature or under refrigeration for up to 60 days

Injection

Store intact vials at room temperature, begin infusion within 4 hours of reconstitution

Medication Administration and Monitoring

Oral

Any be administered with or without food, for suspension shake well

IV

Should be administered over at least 2 hours, do not administer rapidly or bolus injection

□ CBC and platelet count with differential, liver function, and renal function at baseline and periodically during therapy; blood glucose (if symptoms of hypoglycemia occur)

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