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

CellCept Package Insert

CellCept Patient Medication Guide

CellCept Copay Card

Myfortic Package Insert

Myfortic Patient Medication Guide

Myfortic Copay Card

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

- May 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)

Ophthalmologic exam within the first year of prolonged or high-dose treatment (fundus examination plus visual fields and spectral-domain optical coherence tomography if maculopathy is present) to screen for retinal toxicity, followed by annual screening beginning after 3 to 5 years of use (or sooner if major risk factors are present)

Updated June 2023–ARP Practice Committee