# Mycophenolate (Cellcept, Myfortic)

Mycophenolate exhibits cytostatic and reversible effect on T and B lymphocytes by 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.

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

## Resources from Manufacturer

CellCept Prescribing Information
CellCept Patient Medication Guide
CellCept Copay Card
Myfortic Prescribing Information
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, glucocorticoid 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
- Systemic Lupus erythematosus (SLE), 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

## 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).

# ACR/ARP Medication Guide

American College of Rheumatology
*Empowering Rheumatology Professionals*

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*The Interprofessional Division of the American College of Rheumatology*

## Black Box Warnings

- Use during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations. Avoid if safer treatment options are available. Females of reproductive potential must be counseled regarding pregnancy prevention and planning.
- Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Myfortic®.
- Increased risk of development of lymphoma and other malignancies, particularly of the skin.
- Increased susceptibility to infections, including opportunistic infections and severe infections with fatal outcomes.

## Warnings and Precautions

- New or reactivated viral infections: consider reducing dose
- Blood dyscrasias: monitor for neutropenia or red blood cell aplasia
- May cause CNS depression which may impair physical or mental abilities
- Gastrointestinal Complications: Monitor for complications such as bleeding, ulceration and perforations, particularly in patients with underlying gastrointestinal disorders
- Acute Inflammatory Syndrome Associated with Mycophenolate Products: Monitor for this paradoxical inflammatory reaction
- 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, avoid use
- Local Reactions with Rapid Intravenous Administration: Intravenous must not be administered by rapid or bolus intravenous injection.
- 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

***See full prescribing information for further information.***

## Adverse Reactions

Most common adverse reactions (>20%): anemia, leukopenia, constipation, nausea, vomiting, diarrhea, dyspepsia, infections including urinary tract infections and CMV infections, insomnia and postoperative pain. See full prescribing information for further information.

## 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

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

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