

## **MYCOPHENOLATE MOFETIL 500MG TAB**

**CLASS:** Immunosuppressant Agent

**INDICATIONS:** Prophylaxis of organ rejection concomitantly with cyclosporine and corticosteroids in patients receiving allogeneic renal (CellCept®, Myfortic®), cardiac (CellCept®), or hepatic (CellCept®) transplants

### **AVAILABLE DOSAGE FROM THE HOSPITAL:**

MYCOPHENOLATE MOFETIL 500MG TAB, MYCOPHENOLATE SODIUM 360MG TAB

### **TRADE NAMES:**

### **DOSAGE:**

- **Dosing Adult:** *Note:* May be used I.V. for up to 14 days; transition to oral therapy as soon as tolerated.

#### **Renal transplant: *CellCept®:***

Oral: 1 g twice daily. Doses >2 g daily are not recommended.

I.V.: 1 g twice daily

*Myfortic®:* Oral: 720 mg twice daily (1440 mg daily)

#### **Cardiac transplantation: *CellCept®:***

Oral: 1.5 g twice daily

I.V.: 1.5 g twice daily

#### **Hepatic transplantation: *CellCept®:***

Oral: 1.5 g twice daily

I.V.: 1 g twice daily

**Autoimmune hepatitis, refractory (unlabeled use): *CellCept®:*** Oral: 2 g daily (Manns, 2010)

#### **Lupus nephritis (unlabeled use): *CellCept®:*** Oral:

Induction: 1 g twice daily for 6 months in combination with a glucocorticoid (Ong, 2005) **or** 2-3 g daily for 6 months in combination with glucocorticoids (Hahn, 2012)

Maintenance: 0.5-3 g daily (Contreras, 2004) **or** 1 g twice daily (Dooley, 2011) **or** 1-2 g daily (Hahn, 2012)

**Myasthenia gravis (unlabeled use): *CellCept®:*** Oral: 1 g twice daily (range: 1-3 g daily) (Cahoon, 2006; Ciafaloni, 2001; Merriggioli, 2003)

**Psoriasis, moderate-to-severe (unlabeled use):** *CellCept*®: Oral: 2-3 g daily (Menter, 2009)

- **Dosing: Geriatric**

Dosage is the same as younger patients, however, dosing should be cautious due to possibility of increased hepatic, renal, or cardiac dysfunction. Elderly patients may be at an increased risk of certain infections, gastrointestinal hemorrhage, and pulmonary edema, as compared to younger patients.

- **Dosing: Renal Impairment**

Renal transplant: GFR <25 mL/minute/1.73 m<sup>2</sup> in patients outside the immediate post-transplant period:

*CellCept*®: Doses of >1 g administered twice daily should be avoided; patients should also be carefully observed; no dose adjustments are needed in renal transplant patients experiencing delayed graft function postoperatively

*Myfortic*®: No dose adjustments are needed in renal transplant patients experiencing delayed graft function postoperatively; however, monitor carefully for potential concentration dependent adverse events

Cardiac or liver transplant: No data available; mycophenolate may be used in cardiac or hepatic transplant patients with severe chronic renal impairment if the potential benefit outweighs the potential risk.

Hemodialysis: Not removed; supplemental dose is not necessary.

Peritoneal dialysis: Supplemental dose is not necessary.

- **Dosing: Hepatic Impairment**

No dosage adjustment is recommended for renal patients with severe hepatic parenchymal disease; however, it is not currently known whether dosage adjustments are necessary for hepatic disease with other etiologies.

- **Dosing: Adjustment for Toxicity**

Neutropenia (ANC <1.3 x 10<sup>3</sup>/μL): Dosing should be interrupted or the dose reduced, appropriate diagnostic tests performed and patients managed appropriately

## **COMMON SIDE EFFECT:**

**>20%:**

- Cardiovascular: Hypertension (28% to 78%), hypotension (33%), peripheral edema (27% to 64%), edema (27% to 28%), chest pain (26%), tachycardia (20% to 22%)
- Central nervous system: Pain (31% to 76%), headache (16% to 54%), insomnia (41% to 52%), fever (21% to 52%), dizziness (29%), anxiety (28%)
- Dermatologic: Rash (22%)
- Endocrine & metabolic: Hyperglycemia (44% to 47%), hypercholesterolemia (41%), hypomagnesemia (39%), hypokalemia (32% to 37%), hypocalcemia (30%), hyperkalemia (22%)
- Gastrointestinal: Abdominal pain (25% to 63%), nausea (20% to 55%), diarrhea (31% to 51%), constipation (19% to 41%), vomiting (33% to 34%), anorexia (25%), dyspepsia (22%)
- Genitourinary: Urinary tract infection (37%)
- Hematologic: Leukopenia (23% to 46%), anemia (26% to 43%; hypochromic 25%), leukocytosis (22% to 41%), thrombocytopenia (24% to 38%)
- Hepatic: Liver function tests abnormal (25%), ascites (24%)
- Neuromuscular & skeletal: Back pain (35% to 47%), weakness (35% to 43%), tremor (24% to 34%), paresthesia (21%)
- Renal: Creatinine increased (39%), BUN increased (35%), kidney function abnormal (22% to 26%)
- Respiratory: Dyspnea (31% to 37%), respiratory tract infection (22% to 37%), pleural effusion (34%), cough (31%), lung disorder (22% to 30%), sinusitis (26%)
- Miscellaneous: Infection (18% to 27%), sepsis (27%), lactate dehydrogenase increased (23%), *Candida* (17% to 22%), herpes simplex (10% to 21%)

## **PREGNANCY RISK FACTORS: D**