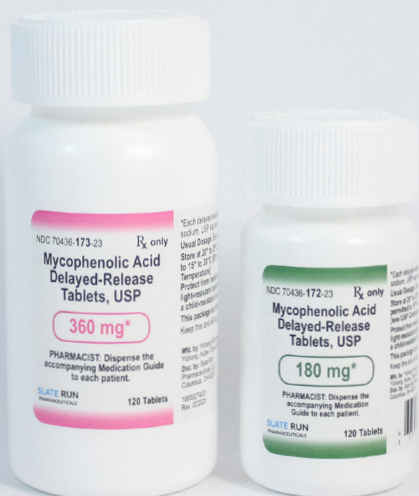


MYCOPHENOLIC ACID

DELAYED-RELEASE TABLETS, USP



To most, “generics” means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.

PRODUCT DETAILS

- Strength: Available in 180 mg and 360 mg delayed-release tablets
- Therapeutic Class: Immunosuppressive Agent

NDC Numbers:

180 mg | Bottle of 120: **70436-172-23**

360 mg | Bottle of 120: **70436-173-23**

To place an order or learn more, call **844-529-8988 (Toll Free)** or email

sales@slaterunpharma.com

6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

NDC: 70436-172-23

Cardinal Health: 5730502
McKesson: 2338002
Amerisource: 10259280

NDC: 70436-173-23

Cardinal Health: 5730510
McKesson: 2338010
Amerisource: 10259281

See reverse side for important safety information.

— MAKING —
GENERICS
REMARKABLE

IMPORTANT SAFETY INFORMATION FOR: MYCOPHENOLIC ACID DELAYED-RELEASE TABLETS, USP

WARNING: EMBRYO-FETAL TOXICITY, MALIGNANCIES, AND SERIOUS INFECTIONS

- Use during pregnancy is associated with increased risks of pregnancy loss and congenital malformations. Avoid if safer treatment options are available. Females of reproductive potential must be counseled regarding pregnancy prevention and planning.
- Increased risk of development of lymphoma and other malignancies, particularly of the skin, due to immunosuppression.
- Increased susceptibility to bacterial, viral, fungal, and protozoal infections, including opportunistic infections.
- Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe mycophenolic acid delayed-release tablets. Patients receiving mycophenolic acid delayed-release tablets should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Mycophenolic Acid Delayed-Release Tablets are contraindicated in patients with a hypersensitivity to mycophenolate sodium, mycophenolic acid (MPA), mycophenolate mofetil, or to any of its excipients.

Polyomavirus associated nephropathy, JC virus associated progressive multifocal leukoencephalopathy, cytomegalovirus (CMV) infections, reactivation of hepatitis B or hepatitis C have been reported in patients treated with immunosuppressants, including mycophenolic acid delayed-release tablets. Reduction in immunosuppression should be considered for patients who develop evidence of new or reactivated viral infections. Physicians should also consider the risk that reduced immunosuppression represents to the functioning allograft.

Cases of pure red cell aplasia (PRCA) have been reported in patients treated with MPA derivatives in combination with other immunosuppressive agents. Patients receiving mycophenolic acid delayed-release tablets should be monitored for blood dyscrasias (e.g., neutropenia or anemia). If blood dyscrasias occur, dosing with mycophenolic acid delayed-release tablets should be interrupted or the dose reduced, appropriate tests performed, and the patient managed accordingly.

Gastrointestinal bleeding (requiring hospitalization), intestinal perforations, gastric ulcers, and duodenal ulcers have been reported in patients treated with mycophenolic acid delayed-release tablets.

During treatment with mycophenolic acid delayed-release tablets, the use of live attenuated vaccines should be avoided and patients should be advised that vaccinations may be less effective.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to mycophenolate during pregnancy and those becoming pregnant within 6 weeks of discontinuing mycophenolic acid delayed-release tablets treatment. To report a pregnancy or obtain information about the registry, visit www.mycophenolateREMS.com or call 1-800-617-8191.

Most common adverse reactions ($\geq 20\%$) include anemia, leukopenia, constipation, nausea, diarrhea, vomiting, dyspepsia, urinary tract infection, CMV infection, insomnia, and postoperative pain.

Please see the package insert for Mycophenolic Acid Delayed-Release Tablets for full prescribing information.