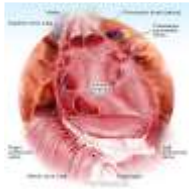
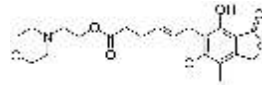


# Rx MYCOPHENOLATE MOFETIL

(Mycophenolate is used in combination with other medications to keep your body from attacking and rejecting your transplanted organ)



## USES

Mycophenolate is used in combination with other medications to keep your body from attacking and rejecting your transplanted organ (e.g., kidney, liver, heart). It belongs to a class of medications called immunosuppressants. This medication works by lowering your body's immune system activity.

## HOW TO USE

Read the Medication Guide provided by your pharmacist before you start taking mycophenolate and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication as directed, usually twice daily on an empty stomach, one hour before or two hours after meals. Swallow this medication whole. Do not crush or chew. If you are taking the capsules, do not open them before swallowing. Certain drugs may decrease the amount of mycophenolate that your body absorbs if taken at the same time. Do not take this medication at the same time as antacids containing aluminum and/or magnesium, cholestyramine, colestipol, or calcium-free phosphate binders (e.g., aluminum products, lanthanum, sevelamer). For more details, ask your pharmacist. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same times each day. Dosage is based on your medical condition and response to therapy. Take this medication exactly as prescribed by your doctor. Do not skip any doses. It is very important to continue taking this medication even if you feel well. Do not stop taking mycophenolate without first talking to your doctor.

## SIDE EFFECTS

See also Warnings section. Constipation, nausea, headache, dizziness, diarrhea, vomiting, stomach upset, loss of appetite, gas, tremor, or trouble sleeping may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Because this medication weakens your immune system, you are more likely to develop infections which may be serious. Tell your doctor immediately if you develop any of the following signs of infection: persistent sore throat/fever, night sweats, flu-like symptoms, painful urination, vision changes, a sore or wound on the skin that feels warm/tender/painful and appears reddened. Tell your doctor immediately if any of these unlikely but serious side effects occur: unusual tiredness, fast/irregular heartbeat, muscle weakness, easy bleeding/bruising, swelling of the feet or ankles, mental/mood changes, weakness on one side of the body, unusual change in the amount of urine. Seek immediate medical attention if any of these rare but very serious side effects occur: chest pain, stomach/abdominal pain, black/tarry stools, vomit that looks like coffee grounds, shortness of breath/rapid breathing. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

## PRECAUTIONS

Before taking mycophenolate mofetil, tell your doctor or pharmacist if you are allergic to it; or to mycophenolic acid, or mycophenolate sodium; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: any type of cancer, kidney disease, liver disease, stomach/intestinal problems (e.g., ulcers), rare genetic disorders (e.g., Lesch-Nyhan or Kelley-Seegmiller syndromes). If you had a kidney transplant and the new kidney does not work properly even though you are taking this medication, the amount of mycophenolate in your body may increase, which can result in increased side effects. This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. Mycophenolate may cause swelling and growth of the gums (gingival hyperplasia). Brush and floss your teeth daily, and see your dentist regularly. Because this medication may increase your risk of developing skin cancers, it is best to avoid prolonged sun exposure, tanning booths and sunlamps while you are using this medication. Use a sunscreen and wear protective clothing when outdoors. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Avoid contact with people who have the flu or any other infection. Notify your doctor if you are scheduled for any kind of test or surgery involving your colon (e.g., colonoscopy, abdominal surgery) that requires cleaning out your colon before the procedure. Removing the bacteria in your digestive tract can decrease the amount of mycophenolate in your body. Caution is advised when using this drug in the elderly because they are less able to remove this drug from their bodies, and therefore may be more sensitive to its effects. This medication is not recommended for use during pregnancy because of possible harm to the unborn baby. Discuss the risks and benefits with your doctor. Women of childbearing age should have a negative pregnancy test within 1 week of starting this medication. Also, use two reliable forms of birth control starting 4 weeks before beginning therapy, and continue for at least 6 weeks after mycophenolate is stopped. Consult your doctor for more details. It is not known whether this drug passes into breast milk, but it may

have undesirable effects on a nursing infant. Therefore, breast-feeding is not recommended while using this drug and for 6 weeks after stopping mycophenolate. If you must take the drug while you are producing milk, but wish to resume breast-feeding six weeks after treatment is finished, pump your breast milk and discard. Consult your doctor for more details.

## DRUG INTERACTIONS

See also How to Use section. Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. This drug should not be used with the following medications because very serious interactions may occur: azathioprine, cholestyramine, colestipol, live vaccines, natalizumab. If you are currently using any of these medications listed above, tell your doctor or pharmacist before starting mycophenolate. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: antacids containing aluminum and/or magnesium, antivirals (e.g., acyclovir, ganciclovir, valganciclovir), calcium-free phosphate binders (e.g., aluminum products, lanthanum, sevelamer), rifampin. This medication may decrease the effectiveness of combination-type birth control pills by decreasing the amount of certain hormones in your system (impaired enterohepatic recirculation or hepatic induction). This can result in pregnancy. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist for details. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

## OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

## MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

## STORAGE

Store the US product at room temperature at 77 degrees F (25 degrees C). Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Store the Canadian product at room temperature between 59 and 86 degrees F (15 and 30 degrees C). Store away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product. **MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).

**WARNING:** Mycophenolate decreases the body's ability to protect against illness and infection, and may also increase your risk of developing lymph node tumors (lymphoma) and other types of tumors. Therefore, this medication must only be given under close medical supervision. Discuss the risks of taking mycophenolate with your doctor.

Notify your doctor immediately if you develop signs of infection (such as persistent sore throat or fever) or other symptoms such as weight loss, night sweats, enlarged lymph nodes, or skin growths.

Women of childbearing age must use two reliable forms of birth control when using mycophenolate, since it may harm an unborn baby. (See also Precautions).

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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