

- cholestyramine (Questran Light®, Questran®, Locholest Light, Locholest, Prevalite®).

Know the medicines you take. Keep a list of them to show to your doctor or nurse and pharmacist when you get a new medicine. Do not take any new medicine without talking with your doctor.

How should I take mycophenolate mofetil?

- Take mycophenolate mofetil exactly as prescribed.
- Do not stop taking mycophenolate mofetil or change the dose unless your doctor tells you to.
- If you miss a dose of mycophenolate mofetil, or you are not sure when you took your last dose, take your prescribed dose of mycophenolate mofetil as soon as you remember. If your next dose is less than 2 hours away, skip the missed dose and take your next dose at your normal scheduled time. Do not take 2 doses at the same time. Call your doctor if you are not sure what to do.
- Take mycophenolate mofetil capsules and tablets on an empty stomach, unless your doctor tells you otherwise. Do not crush mycophenolate mofetil tablets.
- Do not open or crush mycophenolate mofetil capsules
- If you are not able to swallow mycophenolate mofetil tablets or capsules, your doctor may prescribe mycophenolate mofetil oral suspension. This is a liquid form of mycophenolate mofetil. Your pharmacist will mix the medicine before you pick it up from a pharmacy.
- Do not mix mycophenolate mofetil oral suspension with any other medicine. Mycophenolate mofetil oral suspension should not be mixed with any type of liquids before taking the dose.
- Do not breathe in (inhale) or let mycophenolate mofetil powder or oral suspension come in contact with your skin or mucous membranes.
 - If you accidentally get the powder or oral suspension on the skin, wash the area well with soap and water.
 - If you accidentally get the powder or oral suspension in your eyes or other mucous membranes, flush with plain water.
- If you take too much mycophenolate mofetil, call your doctor or the poison control center right away.

What should I avoid while taking mycophenolate mofetil?

- Avoid becoming pregnant. See "What is the most important information I should know about mycophenolate mofetil?"
- Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take mycophenolate mofetil have a higher risk of getting skin cancer (See "What is the most important information I should know about mycophenolate mofetil?"). Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor. This is especially important if your skin is very fair or if you have a family history of skin cancer.
- If you are stopping or donating blood while taking mycophenolate mofetil and for at least 6 weeks after stopping mycophenolate mofetil.
- You should not donate sperm while taking mycophenolate mofetil and for 90 days after stopping mycophenolate mofetil.
- Mycophenolate mofetil may influence your ability to drive and use machines (See "What are the possible side effects of mycophenolate mofetil?"). If you experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with mycophenolate mofetil, you should be cautious about driving or using heavy machines.

What are the possible side effects of mycophenolate mofetil?

- Mycophenolate mofetil can cause serious side effects, including:**
- See "What is the most important information I should know about mycophenolate mofetil?"
 - Low blood cell counts.** People taking high doses of mycophenolate mofetil each day may have a decrease in blood counts, including:
 - white blood cells, especially neutrophils.** Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white blood cell count is low. This is most common from 1 to 6 months after your transplant.
 - red blood cells.** Red blood cells carry oxygen to your body tissues. You have a higher chance of getting severe anemia when your red blood cell count is low.

- placenta.** Placenta helps before you start taking mycophenolate mofetil and during treatment with mycophenolate mofetil to check your blood cell counts. Tell your doctor right away if you have any signs of infection (See "What is the most important information I should know about mycophenolate mofetil?"), including any unexpected bruising or bleeding. Also, tell your doctor if you have unusual tiredness, lack of energy, dizziness, or fainting.
- Stomach problems.** Stomach problems including intestinal bleeding, a tear in your intestinal wall (perforation) or stomach ulcers can happen in a person who take mycophenolate mofetil. Bleeding can be severe and you may have to be hospitalized for treatment. Call your doctor right away if you have sudden or severe stomach-area pain or stomach-area pain that does not go away, if you have diarrhea.

- The most common side effects of mycophenolate mofetil include:**
- diarrhea
 - blood problems including low white and red blood cell counts
 - infections
 - blood pressure problems
 - fast heart beat
 - swelling of the lower legs, ankles and feet
 - changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia)
 - stomach problems including diarrhea, constipation, nausea and vomiting
 - rash
 - neurotic system problems such as headache, dizziness and tremor

- Side effects that can happen more often in children than in adults taking mycophenolate mofetil include:**
- stomach area pain
 - diarrhea
 - vomiting
 - sore throat
 - colds (respiratory tract infections)
 - high blood pressure
 - low white blood cell count
 - low red blood cell count

These are not all of the possible side effects of mycophenolate mofetil. Tell your doctor about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Strides Pharma Inc. at 1-877-244-9825 or go to www.strides.com

How should I store mycophenolate mofetil capsules and tablets?

- Store mycophenolate mofetil capsules and tablets at room temperature between 20° to 25°C (68° to 77°F). Dispense in light-resistant containers, such as the manufacturer's original containers.
- Keep mycophenolate mofetil tablets in light resistant container that it comes in.

Keep mycophenolate mofetil and all medicines out of the reach of children.

General information about the safe and effective use of mycophenolate mofetil. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mycophenolate mofetil for a condition for which it was not prescribed. Do not give mycophenolate mofetil to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about mycophenolate mofetil. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about mycophenolate mofetil that is written for health professionals.

What are the ingredients in mycophenolate mofetil capsules and tablets?

Active ingredient: mycophenolate mofetil

Inactive ingredients:

Mycophenolate mofetil 250 mg capsules: croscarmellose gum, magnesium stearate, povidone [K-30], microcrystalline cellulose. The capsule shells contain yellow iron oxide, FD&C red #3, gelatin, sodium lauryl sulfate, and titanium dioxide.

Mycophenolate mofetil 500 mg tablets: croscarmellose gum, magnesium stearate (Vegetable), povidone [K-30], microcrystalline cellulose, opadry brown.

The opadry brown contains FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, Hypromellose, iron oxide red, polyethylene glycol and titanium dioxide.

Manufactured by:
Strides Pharma Science Ltd.
Bangluru - 562106, India

Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816

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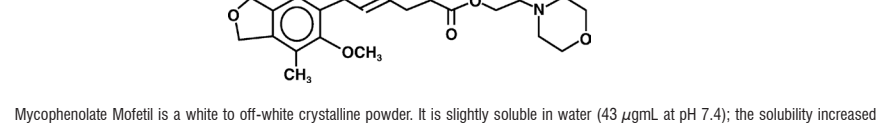
This Medication Guide has been approved by the U.S. Food and Drug Administration.

The experience with overdose of mycophenolate mofetil in humans is limited. The reported effects associated with overdose fall within the known safety profile of the drug. The highest overdose of mycophenolate mofetil in clinical trials was 4.5 g/day for 3 days. At doses of 4.5 g/day for 3 days, there appeared to be higher rates compared to the use of 2 g/day in terms of gastrointestinal intolerance (nausea, vomiting, and/or diarrhea), and occasional hematologic abnormalities, particularly neutropenia (see Warnings and Precautions 4.2).

Treatment and Management
MPA and its active diester glucuronide metabolites of MPA (MPAG) are usually not removed by hemodialysis. However, at high MPAG plasma concentrations (>100 mg/mL), small amounts of MPAG are removed by increasing excretion of the drug. MPA can be removed by live acid excretors, such as cholestyramine (see Clinical Pharmacology 12.1).

11. DESCRIPTION
Mycophenolate mofetil is an antiproliferative immunosuppressant. It is the 2-morpholinoethyl ester of mycophenolic acid (MPA), an immunosuppressive agent whose mechanism of immunosuppression (IMiP) is unclear.

The chemical name for mycophenolate mofetil (MPM) is 2-morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-2-methyl-2H-pyridin-3-yl)-3-crotonamido-5-methyl-4-isoxazole-3-carboxylate. It has an empirical formula of C₂₄H₃₀N₂O₇, a molecular weight of 453.50, and the following structural formula:



Mycophenolate Mofetil is a white to off-white crystalline powder. It is slightly soluble in water (4.5 mg/mL at pH 7.4), the solubility increased in acidic media (6.72 mg/mL at pH 5.0). It is freely soluble in acetone, soluble in methanol and sparingly soluble in ethanol. The apparent partition coefficient in 1-octanol/water (pH 7.4) buffer solution is 238. The pKa values for MPM are 4.5 for the protons on the pyridine ring and 8.5 for the protons on the crotonic acid.

Mycophenolate mofetil is available for oral administration as tablets for oral administration as capsules containing 250 mg of MPA. Tablets contain 500 mg of MPM.

MPAG is available as mycophenolate mofetil capsules, USP 250 mg include croscarmellose gum, magnesium stearate, povidone [K-30], microcrystalline cellulose. The capsule shells contain yellow iron oxide, FD&C red #3, gelatin, sodium lauryl sulfate, and titanium dioxide.

Inactive ingredients in mycophenolate mofetil tablets, USP 500 mg include croscarmellose gum, magnesium stearate (Vegetable), povidone [K-30], microcrystalline cellulose, and titanium dioxide.

The opadry brown contains FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, Hypromellose, iron oxide red, polyethylene glycol and titanium dioxide.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Mycophenolate mofetil is an orally absorbed thymidine and deoxythymidine triphosphate (dTMP) and dUDP inhibitor. It acts as a selective, reversible, and reversible inhibitor of inosine monophosphate dehydrogenase (IMPDH), and therefore inhibits the de novo synthesis of purines and pyrimidines. IMPDH is a key enzyme in the de novo synthesis of purines and pyrimidines. IMPDH is a key enzyme in the de novo synthesis of purines and pyrimidines. IMPDH is a key enzyme in the de novo synthesis of purines and pyrimidines.

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