MEDICATION GUIDE
Mycophenolate Mofetil Tablets, USP
(mye'' koe fen' oh late moe' fe til)

Read the Medication Guide that comes with mycophenolate mofetil tablets before you start taking it and each time you refill your prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about mycophenolate mofetil tablets?

Mycophenolate mofetil tablets can cause serious side effects, including:

Increased risk of loss of a pregnancy (miscarriage) and higher risk of birth defects. Females who take mycophenolate mofetil tablets during pregnancy have a higher risk of miscarriage during the first 3 months (first trimester), and a higher risk that their baby will be born with birth defects.

- **If you are a female who can become pregnant**, your doctor must talk with you about acceptable birth control methods (contraceptive counseling) to use while taking mycophenolate mofetil tablets. You should have 1 pregnancy test immediately before starting mycophenolate mofetil tablets and another pregnancy test 8 to 10 days later. Pregnancy tests should be repeated during routine follow-up visits with your doctor. Talk to your doctor about the results of all of your pregnancy tests.
  You must use acceptable birth control during your entire mycophenolate mofetil tablets treatment and for 6 weeks after stopping mycophenolate mofetil tablets, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely. Mycophenolate mofetil tablets decreases blood levels of the hormones in birth control pills that you take by mouth. Birth control pills may not work as well while you take mycophenolate mofetil tablets, and you could become pregnant. If you take birth control pills while using mycophenolate mofetil tablets you must also use another form of birth control. Talk to your doctor about other birth control methods that you can use while taking mycophenolate mofetil tablets.
- **If you are a sexually active male whose female partner can become pregnant while you are taking mycophenolate mofetil tablets**, use effective contraception during treatment and for at least 90 days after stopping mycophenolate mofetil tablets.
- **If you plan to become pregnant**, talk with your doctor. Your doctor will decide if other medicines to prevent rejection may be right for you.
- **If you become pregnant while taking mycophenolate mofetil tablets, do not stop taking mycophenolate mofetil tablets. Call your doctor right away.** You and your doctor may decide that other medicines to prevent rejection may be right for you. You and your doctor should report your pregnancy to the Mycophenolate Pregnancy Registry either:
  - o By phone at 1-800-617-8191 **or**
  - o By visiting the REMS website at: **www.mycophenolateREMS.com**

The purpose of this registry is to gather information about the health of you and your baby.

Increased risk of getting certain cancers. People who take mycophenolate mofetil tablets have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your doctor if you have:

- unexplained fever, prolonged tiredness, weight loss or lymph node swelling
- a brown or black skin lesion with uneven borders, or one part of the lesion does not look like the other
- a change in the size and color of a mole
- a new skin lesion or bump
- any other changes to your health

Increased risk of getting serious infections. Mycophenolate mofetil tablets weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with mycophenolate mofetil tablets and can lead to hospitalizations and death. These serious infections can include:

- **Viral infections.** Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with mycophenolate mofetil tablets include:
  - o Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.
  - o BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
  - o Hepatitis B and C viruses. Hepatitis viruses can affect how your liver works. Talk to your doctor about how hepatitis viruses may affect you.
  - o COVID-19
- **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** In some patients, mycophenolate mofetil tablets may cause an infection of the brain that may cause death. You are at risk for this brain infection because you have a weakened immune system. Call your doctor right away if you have any of the following symptoms:
  - o weakness on one side of the body
  - o you do not care about things you usually care about (apathy)
  - o you are confused or have problems thinking
  - o you cannot control your muscles
- **Fungal infections**. Yeasts and other types of fungal infections can happen with mycophenolate mofetil tablets and can cause serious tissue and blood infections (See **"What are the possible side effects of mycophenolate mofetil tablets?**").

Call your doctor right away if you have any of the following signs and symptoms of infection:

- temperature of 100.5°F or greater
- cold symptoms, such as a runny nose or sore throat
- flu symptoms, such as an upset stomach,
- earache or headache
- pain during urination
- white patches in the mouth or throat
- unexpected bruising or bleeding
- cuts, scrapes or incisions that are red, stomach pain, vomiting or diarrhea warm and oozing pus

See **"What are the possible side effects of mycophenolate mofetil tablets?"** for information about other serious side effects.

What are mycophenolate mofetil tablets?

- Mycophenolate mofetil tablets are a prescription medicine to prevent rejection (antirejection medicine) in people who have received a kidney, heart or liver transplant. Rejection is when the body's immune system perceives the new organ as a "foreign" threat and attacks it.
- Mycophenolate mofetil tablets are used with other medicines containing cyclosporine and corticosteroids.

Who should not take mycophenolate mofetil tablets?

Do not take mycophenolate mofetil tablets if you have a history of allergic reactions to mycophenolate mofetil or any of the ingredients in mycophenolate mofetil tablets. See the end of this Medication Guide for a complete list of ingredients in mycophenolate mofetil tablets.

What should I tell my doctor before taking mycophenolate mofetil tablets?

Tell your doctor about all of your medical conditions, including if you:

- have any digestive problems, such as ulcers.
- have Lesch-Nyhan syndrome, Kelley-Seegmiller syndrome, or another rare inherited deficiency hypoxanthine-guanine phosphoribosyltransferase (HGPRT). You should not take mycophenolate mofetil tablets if you have one of these disorders.
- plan to receive any vaccines. People taking mycophenolate mofetil tablets should not receive live vaccines. Some vaccines may not work as well during treatment with mycophenolate mofetil tablets.
- are pregnant or plan to become pregnant. See **"What is the most important information I should know about mycophenolate mofetil tablets?"**
- are breastfeeding or plan to breastfeed. It is not known if mycophenolate mofetil passes into breast milk. You and your doctor will decide if you will take mycophenolate mofetil tablets or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Some medicines may affect the way mycophenolate mofetil tablets works, and mycophenolate mofetil tablets may affect how some medicines work.

Especially tell your doctor if you take:

- birth control pills (oral contraceptives). See **"What is the most important information I should know about mycophenolate mofetil tablets?"**
- sevelamer (Renagel®, Renvela™). These products should be taken at least 2 hours after taking mycophenolate mofetil tablets.
- acyclovir (Zovirax®), valacyclovir (Valtrex®), ganciclovir (CYTOVENE®-IV, Vitrasert®), valganciclovir (VALCYTE®).
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®).
- antacids that contain magnesium and aluminum (mycophenolate mofetil tablets and the antacid should not be taken at the same time).
- proton pump inhibitors (PPIs) (Prevacid®, Protonix®).
- sulfamethoxazole/trimethoprim (BACTRIM™, BACTRIM DS™).
- norfloxacin (Noroxin®) and metronidazole (Flagyl®, Flagyl® ER, Flagyl® IV, Metro IV, Helidac®, Pylera™).
- ciprofloxacin (Cipro®, Cipro®XR, Ciloxan®, Proquin®XR) and amoxicillin plus clavulanic acid (Augmentin®, Augmentin XR™).
- azathioprine (Azasan®, Imuran®).
- 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.

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How should I take mycophenolate mofetil tablets?

- Take mycophenolate mofetil tablets exactly as prescribed.
- **Do not** stop taking mycophenolate mofetil tablets or change the dose unless your doctor tells you to.
- If you miss a dose of mycophenolate mofetil tablets, or you are not sure when you took your last dose, take your prescribed dose of mycophenolate mofetil tablets 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 tablets on an empty stomach, unless your doctor tells you otherwise. **Do not** crush mycophenolate mofetil tablets.
- If you are not able to swallow mycophenolate mofetil tablets, your doctor may prescribe mycophenolate mofetil oral suspension.
- 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 tablets?

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

What are the possible side effects of mycophenolate mofetil tablets?

Mycophenolate mofetil tablets may cause serious side effects, including:

- See **"What is the most important information I should know about mycophenolate mofetil tablets?"**
- **Low blood cell counts.** People taking high doses of mycophenolate mofetil tablets each day may have a decrease in blood counts, including:
  - o **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 month to 6 months after your transplant.
  - o **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.
  - o **platelets.** Platelets help with blood clotting.

Your doctor will do blood tests before you start taking mycophenolate mofetil tablets and during treatment with mycophenolate mofetil tablets 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 tablets?"**), 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 people who take mycophenolate mofetil tablets. 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, or if you have diarrhea.
- **Inflammatory reactions.** Some people taking mycophenolate mofetil tablets may have an inflammatory reaction with fever, joint stiffness, joint pain, and muscle pain. Some of these reactions may require hospitalization.This reaction could happen within weeks to months after your treatment with mycophenolate mofetil tablets starts or if your dose is increased. Call your doctor right away if you experience these symptoms.
- **Allergic (hypersensitivity) reactions.** Allergic reactions, including a severe allergic reaction called anaphylaxis, can happen after taking mycophenolate mofetil tablets. Stop taking mycophenolate mofetil tablets and get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of the face, lips, tongue, or throat
  - rash, hives, or itching
  - fainting, dizziness, feeling lightheaded
  - trouble breathing or swallowing
  - fast heartbeat
  - chest pain

The most common side effects of mycophenolate mofetil tablets include:

- diarrhea
- blood problems including low white and red blood cell counts
- infections
- blood pressure problems
- fast heartbeat
- 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
- nervous system problems such as headache, dizziness and tremor

Side effects that can happen more often in children than in adults taking mycophenolate mofetil tablets include:

- stomach area pain
- fever
- infection
- pain
- blood infection (sepsis)
- 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 tablets. 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 Hetero Labs Limited at 1-866-495-1995.

How should I store mycophenolate mofetil tablets?

- Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in light-resistant containers.
- Keep mycophenolate mofetil tablets in the light resistant container that it comes in.

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

General information about the safe and effective use of mycophenolate mofetil tablets.

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

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

What are the ingredients in mycophenolate mofetil tablets?

Active ingredient: mycophenolate mofetil USP

Inactive ingredients:

croscarmellose sodium, magnesium stearate, microcrystalline cellulose and povidone. The tablets are coated with opadry purple which contains FD&C blue #2, hydroxylpropyl cellulose, hypromellose, polyethyelene glycol, red iron oxide and titanium dioxide.

Medication Guide available at http://camberpharma.com/medication-guides

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For more information, call 1-866-495-1995.

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

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