

## MEDICATION GUIDE

### **Mycophenolate Mofetil Capsules, USP Mycophenolate Mofetil Tablets, USP (mye" koe fen' oh late moe' fe til) Rx Only**

Read the Medication Guide that comes with Mycophenolate Mofetil Capsules and/or 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 your treatment.

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

**Mycophenolate can cause serious side effects:**

- **Increased risk of loss of a pregnancy (miscarriage) and higher risk of birth defects.** Females who take mycophenolate 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.
- you should have one pregnancy test immediately before starting mycophenolate 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 therapy and for 6 weeks after stopping mycophenolate, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely.

Mycophenolate 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, and you could become pregnant. If you take birth control pills while using mycophenolate 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.

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, do not stop taking mycophenolate. Call your doctor right away.** In certain situations, you and your doctor may decide that taking mycophenolate is more important to your health than the possible risks to your unborn baby.

- You and your doctor should report your pregnancy to
  - Mycophenolate Pregnancy Registry (1-800-617-8191).

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

- **Increased risk of getting serious infections.** Mycophenolate weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with mycophenolate and can lead to 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 include:
    - Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.
    - BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
    - Hepatitis B and C viruses. Hepatitis viruses can affect how your liver works. Talk to your doctor about how hepatitis viruses may affect you.
  - **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** In some patients, mycophenolate 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. You should tell your doctor right away if you have any of the following symptoms:
    - Weakness on one side of the body
    - You do not care about things that you usually care about (apathy)
    - You are confused or have problems thinking
    - You cannot control your muscles
  - **Fungal infections.** Yeasts and other types of fungal infections can happen with mycophenolate and can cause serious tissue and blood infections (see "**What are the possible side effects of mycophenolate?**")

**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, stomach pain, vomiting or diarrhea
- Earache or headache
- Pain during urination
- White patches in the mouth or throat
- Unexpected bruising or bleeding
- Cuts, scrapes or incisions that are red, warm and oozing pus
- **Increased risk of getting certain cancers.** People who take mycophenolate 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

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

**What is mycophenolate?**

Mycophenolate is 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 is used with other medicines called cyclosporine (Sandimmune®, Gengraf®, Neoral®) and corticosteroids.

Mycophenolate has been used safely and works in children who received a kidney transplant as it does in adults. It is not known if mycophenolate is safe and works in children who receive a heart or liver transplant.

**Who should not take Mycophenolate?**

**Do not take mycophenolate if you are allergic to mycophenolate mofetil or any of the ingredients in Mycophenolate Mofetil Capsules and/or Tablets.** See the end of this Medication Guide for a complete list of ingredients in Mycophenolate Mofetil Capsules and/or Tablets.

**What should I tell my doctor before taking mycophenolate?**

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

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

**Tell your healthcare provider about all of the medicines you are taking including prescription and nonprescription medicines, vitamins and herbal supplements.** Some medicines may affect the way mycophenolate works, and mycophenolate 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?**"
- sevelamer (Renagel®, Renvela™). These products should be taken 2 hours after taking mycophenolate
- acyclovir (Zovirax®), valacyclovir (Valtrex®), ganciclovir (CYTOVENE®-IV, Vitrasert®), Valganciclovir (VALCYTE®)
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)
- antacids that contain magnesium and aluminum (mycophenolate 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<sup>®</sup>, Cipro<sup>®</sup> XR, Ciloxan<sup>®</sup>, Proquin<sup>®</sup> XR) and amoxicillin plus clavulanic acid (Augmentin<sup>®</sup>, Augmentin XR<sup>™</sup>)
- azathioprine (Azasan<sup>®</sup>, Imuran<sup>®</sup>)
- cholestyramine (Questran Light<sup>®</sup>, Questran<sup>®</sup>, Locholest Light, Locholest, Prevalite<sup>®</sup>)

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?

- Take mycophenolate exactly as prescribed.
- Do not stop taking mycophenolate or change the dose unless your doctor tells you to.
- If you miss a dose of mycophenolate, or are not sure when you took your last dose, take the regular amount of mycophenolate prescribed as soon as you remember. If it is time for your next dose, 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/or tablets on an empty stomach, either 1 hour before or 2 hours after a meal, unless your healthcare provider tells you otherwise. With the approval of your healthcare provider, in stable kidney transplant patients, mycophenolate can be taken with food if necessary.
- Most people take Mycophenolate Mofetil Capsules or Tablets by mouth either as blue and brownish orange capsules or lavender tablets. Some people may get mycophenolate soon after their transplant surgery as an infusion into a vein.
- Do not crush Mycophenolate Mofetil Tablets. Do not open or crush Mycophenolate Mofetil Capsules.
- If you are not able to swallow Mycophenolate Mofetil Capsules or Tablets, your doctor may prescribe Mycophenolate Mofetil Oral Suspension. This is a liquid form of mycophenolate. Your pharmacist will mix the medicine before giving it to you.
- If you take too much mycophenolate, call your doctor or the poison control center right away.

#### What should I avoid while taking mycophenolate?

- **Avoid pregnancy.** See “**What is the most important information I should know about mycophenolate?**”
- **Limit the amount of time you spend in sunlight.** Avoid using tanning beds or sunlamps. People who take mycophenolate have a higher risk of getting skin cancer. (See “**What is the most important information I should know about mycophenolate?**”) Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer.

#### What are the possible side effects of mycophenolate?

##### Mycophenolate can cause serious side effects:

- See “**What is the most important information I should know about mycophenolate?**”
- **Low blood cell counts.** People taking high doses of mycophenolate 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 3 months 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.
  - **platelets.** Platelets help with blood clotting.

Your doctor will do blood tests before you start taking mycophenolate and during treatment with mycophenolate 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?**”), or any unexpected bruising or bleeding. Also, tell your doctor if you have unusual tiredness, lack of energy, dizziness or fainting.

- **Stomach problems.** Stomach and intestinal bleeding can happen in people who take high doses of mycophenolate. Bleeding can be severe and you may have to be hospitalized for treatment.

#### Common side effects include:

- diarrhea. Call your doctor right away if you have diarrhea. Do not stop taking mycophenolate without first talking with your doctor.
- vomiting
- pain
- stomach area pain
- swelling of the lower legs, ankles and feet
- high blood pressure

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

- stomach area pain
- fever
- infection
- pain
- blood infection (sepsis)
- diarrhea
- sore throat
- colds (respiratory tract infections)
- high blood pressure
- low white blood cell count
- low red blood cell count
- vomiting

These are not all of the possible side effects of mycophenolate. 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 the FDA at 1-800-FDA-1088 or 1-800-313-4623.

#### How should I store mycophenolate?

- Store Mycophenolate Mofetil Capsules and/or Tablets at room temperature, between 59°F to 86°F (15°C to 30°C). Keep the container closed tightly.
- **Keep Mycophenolate Mofetil Capsules and/or Tablets and all medicines out of the reach of children**

#### General Information about mycophenolate:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mycophenolate for a condition for which it was not prescribed. Do not give mycophenolate 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. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about mycophenolate that is written for healthcare professionals. For more information or additional copies of Medication Guide, please call 1-800-313-4623.

#### What are the ingredients in Mycophenolate Mofetil Capsules and/or Tablets?

**Active Ingredient:** Mycophenolate Mofetil, USP

##### Inactive Ingredients:

Mycophenolate Mofetil 250 mg capsules: croscarmellose sodium, magnesium stearate, povidone (K-90) and pregelatinized starch. The capsule shells contain FD&C blue #2, gelatin, red iron oxide, sodium lauryl sulfate, titanium dioxide, and yellow iron oxide and the printing ink contains shellac, propylene glycol, and black iron oxide.

Mycophenolate Mofetil 500 mg tablets: croscarmellose sodium, FD&C blue #2 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, povidone (K-90), red iron oxide, talc, and titanium dioxide.

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

**CYTOVENE-IV, and VALCYTE** are registered trademarks of Hoffmann-La Roche Inc.

**BACTRIM and BACTRIM DS** are trademarks of Hoffmann-La Roche Inc. Any other trademarks in this document are the property of their respective owners.

#### Manufactured by:

Jubilant Cadista Pharmaceuticals Inc.

Salisbury, MD 21801, USA

0267/MG

Rev. # 08/2015.