

MEDICATION GUIDE

Mycophenolic (my-co-fen-o-lic acid) Acid Delayed-Release Tablets, USP

Medication Guide available at <https://www.apotex.com/products/us/mg.asp>

Read the Medication Guide that comes with mycophenolic acid delayed-release tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have any questions about mycophenolic acid delayed-release tablets, ask your doctor.

What is the most important information I should know about mycophenolic acid delayed-release tablets?

Mycophenolic acid delayed-release tablets can cause serious side effects, including:

- **Increased risk of loss of pregnancy (miscarriage) and higher risk of birth defects.** Females who take mycophenolic acid delayed-release 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.
 - o If you are a female who can become pregnant:
 - your doctor must talk with you about acceptable birth control methods (contraceptive counseling) while taking mycophenolic acid delayed-release tablets.
 - you should have a pregnancy test immediately before starting mycophenolic acid delayed-release 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 mycophenolic acid delayed-release tablets therapy and for 6 weeks after stopping mycophenolic acid delayed-release tablets, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely. Mycophenolic acid delayed-release 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 mycophenolic acid delayed-release tablets and you could become pregnant. If you decide to take birth control pills while using mycophenolic acid delayed-release tablets, you must also use another form of birth control. Talk to your doctor about other birth control methods that can be used while taking mycophenolic acid delayed-release tablets.
 - o If you are a sexually active male whose female partner can become pregnant use effective contraception while you are taking mycophenolic acid delayed-release tablets, for at least 90 days after stopping mycophenolic acid delayed-release 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 mycophenolic acid delayed-release tablets, do not stop taking mycophenolic acid delayed-release 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
 - Mycophenolate Pregnancy Registry (1-800-617-8191)

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

- **Increased risk of getting serious infections.** Mycophenolic acid delayed-release tablets weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with mycophenolic acid delayed-release tablets 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 mycophenolic acid delayed-release tablets 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.
 - COVID-19
 - **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** In some patients mycophenolic acid delayed-release 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. You should tell your healthcare provider 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.** Yeast and other types of fungal infections can happen with mycophenolic acid delayed-release tablets and cause serious tissue and blood infections. **See “What are the possible side effects of mycophenolic acid delayed-release tablets?”**

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

- o Temperature of 100.5°F or greater
- o Cold symptoms, such as a runny nose or sore throat
- o Flu symptoms, such as an upset stomach, stomach pain, vomiting, or diarrhea
- o Earache or headache
- o Pain during urination or you need to urinate often
- o White patches in the mouth or throat
- o Unexpected bruising or bleeding
- o Cuts, scrapes, or incisions that are red, warm, and oozing pus

- **Increased risk of getting certain cancers.** People who take mycophenolic acid delayed-release tablets have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your doctor if you have:

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

See the section “What are the possible side effects of mycophenolic acid delayed-release tablets?” for other serious side effects.

What are mycophenolic acid delayed-release tablets?

Mycophenolic acid delayed-release tablets are a prescription medicine given to prevent rejection (antirejection medicine) in people who have received a kidney transplant. Rejection is when the body's immune system senses the new organ as “foreign” and attacks it.

Mycophenolic acid delayed-release tablets are used with other medicines containing cyclosporine (Sandimmune®, Gengraf®, and Neoral®) and corticosteroids.

Mycophenolic acid delayed-release tablets can be used to prevent rejection in children who are 5 years or older and are stable after having a kidney transplant. It is not known if mycophenolic acid delayed-release tablets are safe and works in children younger than 5 years. It is not known how mycophenolic acid delayed-release tablets works in children who have just received a new kidney transplant.

Who should not take mycophenolic acid delayed-release tablets?

Do not take mycophenolic acid delayed-release tablets if you are allergic to mycophenolic acid (MPA), mycophenolate sodium, mycophenolate mofetil, or any of the ingredients in mycophenolic acid delayed-release tablets. See the end of this Medication Guide for a complete list of ingredients in mycophenolic acid delayed-release tablets.

What should I tell my doctor before I start taking mycophenolic acid delayed-release tablets?

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

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

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Some medicines may affect the way mycophenolic acid delayed-release tablets works and mycophenolic acid delayed-release 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 mycophenolic acid delayed-release tablets?”**
- antacids that contain aluminum or magnesium. Mycophenolic acid delayed-release tablets and antacids should not be taken at the same time.
- acyclovir (Zovirax®), Ganciclovir (Cytovene® IV, Valcyte®)
- azathioprine (Azasan®, Imuran®)

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

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

How should I take mycophenolic acid delayed-release tablets?

- Take mycophenolic acid delayed-release tablets exactly as prescribed. Your healthcare provider will tell you how much mycophenolic acid delayed-release tablets to take.
- Do not stop taking or change your dose of mycophenolic acid delayed-release tablets without talking to your healthcare provider.
- Take mycophenolic acid delayed-release tablets on an empty stomach, either 1 hour before or 2 hours after a meal.
- Swallow mycophenolic acid delayed-release tablets whole. Do not crush, chew, or cut mycophenolic acid delayed-release tablets. The mycophenolic acid delayed-release tablets have a coating so that the medicine will pass through your stomach and dissolve in your intestine.
 - o **If you forget to take mycophenolic acid delayed-release tablets,** take it as soon as you remember and then take your next dose at its regular time. If it is almost time for your next dose, skip the missed dose. Do not take two doses at the same time. Call your doctor or pharmacist if you are not sure what to do.
 - o **If you take more than the prescribed dose of mycophenolic acid delayed-release tablets,** call your doctor right away.
 - o **Do not change (substitute) between using mycophenolic acid delayed-release tablets and mycophenolate mofetil tablets, capsules, or oral suspension for one another unless your healthcare provider tells you to.** These medicines are absorbed differently. This may affect the amount of medicine in your blood.
 - o Be sure to keep all appointments at your transplant clinic. During these visits, your doctor may perform regular blood tests.

What should I avoid while taking mycophenolic acid delayed-release tablets?

- **Avoid pregnancy.** See “What is the most important information I should know about mycophenolic acid delayed-release tablets?”
- Limit the amount of time you spend in sunlight. Avoid using tanning beds and sunlamps. People who take mycophenolic acid delayed-release tablets have a higher risk of getting skin cancer. **See “What is the most important information I should know about mycophenolic acid delayed-release tablets?”** Wear protective clothing when you are in the sun and use a broad-spectrum sunscreen with a high sun protection factor (SPF 30 and above). This is especially important if your skin is fair (light colored) or you have a family history of skin cancer.
- You should not donate blood while taking mycophenolic acid delayed-release tablets and for at least 6 weeks after stopping mycophenolic acid delayed-release tablets.
- You should not donate sperm while taking mycophenolic acid delayed-release tablets and for 90 days after stopping mycophenolic acid delayed-release tablets.
- Elderly patients 65 years of age or older may have more side effects with mycophenolic acid delayed-release tablets because of a weaker immune system.

What are the possible side effects of mycophenolic acid delayed-release tablets?

Mycophenolic acid delayed-release tablets can cause serious side effects.

See “What is the most important information I should know about mycophenolic acid delayed-release tablets?”

Stomach and intestinal bleeding can happen in people who take mycophenolic acid delayed-release tablets. Bleeding can be severe and you may have to be hospitalized for treatment.

Some people taking Mycophenolic acid delayed-release 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 you start treatment with Mycophenolic acid delayed-release tablets or if your dose is increased. Call your doctor right away if you experience these symptoms.

The most common side effects of taking mycophenolic acid delayed-release tablets include:

- In people with a new transplant:
- low blood cell counts
 - o red blood cells
 - o white blood cells
 - o platelets
 - constipation
 - nausea
 - diarrhea
 - vomiting
 - urinary tract infections
 - stomach upset

In people who take mycophenolic acid delayed-release tablets for a long time (long-term) after transplant:

- low blood cell counts
 - o red blood cells
 - o white blood cells
- nausea
- diarrhea
- sore throat

Your healthcare provider will do blood tests before you start taking mycophenolic acid delayed-release tablets and during treatment with mycophenolic acid delayed-release tablets to check your blood cell counts. Tell your healthcare provider right away if you have any signs of infection (**see “What is the most important information I should know about mycophenolic acid delayed-release tablets?”**), or any unexpected bruising or bleeding. Also, tell your healthcare provider if you have unusual tiredness, dizziness, or fainting.

These are not all the possible side effects of mycophenolic acid delayed-release tablets. Your healthcare provider may be able to help you manage these side effects.

Call your doctor for medical advice about side effects.

You may report side effects to

- FDA MedWatch at 1-800-FDA-1088 or
- Apotex Corp. at 1-800-706-5575.

How should I store mycophenolic acid delayed-release tablets?

- Store mycophenolic acid delayed-release tablets at room temperature, 59°F to 86°F (15°C to 30°C). Mycophenolic acid delayed-release tablets do not need to be refrigerated.
- Keep the container tightly closed. Store mycophenolic acid delayed-release tablets in a dry place.
- **Keep mycophenolic acid delayed-release tablets and all medicines out of the reach of children.**

General information about mycophenolic acid delayed-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mycophenolic acid delayed-release tablets for a condition for which it was not prescribed. Do not give mycophenolic acid delayed-release tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about mycophenolic acid delayed-release tablets. If you would like more information, talk with your doctor.

You can ask your doctor or pharmacist for information about mycophenolic acid delayed-release tablets that is written for healthcare professionals. You can also call Apotex Corp. at 1-800-706-5575.

What are the ingredients in mycophenolic acid delayed-release tablets?

Active ingredient: mycophenolic acid (as mycophenolate sodium)

Inactive ingredients: colloidal silicon dioxide, hypromellose, methylcellulose, polyethylene glycol, sodium lauryl sulfate and stearic acid. The enteric coating of the tablet consists of ferric oxide red (360 mg), ferric oxide yellow, indigotine al lake (180 mg), methacrylic acid and ethyl acrylate copolymer dispersion, talc, titanium dioxide and triethyl citrate.

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APOTEX INC.
MYCOPHENOLIC ACID DELAYED-RELEASE TABLETS, USP
180 mg and 360 mg

| Manufactured by | Manufactured for |
|---|--|
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This Medication Guide has been approved by the U.S. Food and Drug Administration.