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## Mycophenolate

pronounced as (mye koe fen' oh late)

### IMPORTANT WARNING:

Risk of birth defects:

Mycophenolate must not be taken by women who are pregnant or who may become pregnant. There is a high risk that mycophenolate will cause miscarriage (loss of the pregnancy) during the first 3 months of pregnancy or will cause the baby to be born with birth defects (problems that are present at birth).

You should not take mycophenolate if you are pregnant or if you may become pregnant. You must have a negative pregnancy test before starting your treatment with mycophenolate, again 8 to 10 days later, and at routine follow-up appointments. You must use acceptable birth control during your treatment, and for 6 weeks after you stop taking mycophenolate. Your doctor will tell you which forms of birth control are acceptable for you to use. Mycophenolate may decrease the effectiveness of oral contraceptives (birth control pills), so it is especially important to use a second form of birth control along with this type of contraceptive.

If you are a male with a female partner who may become pregnant, you should use acceptable birth control during treatment and for at least 90 days after your last dose. Do not donate sperm during your treatment and for at least 90 days after your last dose.

Call your doctor right away if you think you or your partner, is pregnant or if you miss a menstrual period.

Because of the possibility that your donation may go to a female who may be or become pregnant, do not donate blood during your treatment and for at least 6 weeks after your last dose.

Risks of serious infections:

Mycophenolate weakens the body's immune system and may decrease your ability to fight infection. Wash your hands often and avoid people who are sick while you are taking this medication. If you experience any of the following symptoms, call your doctor immediately: fever, sore throat, chills, or cough; unusual bruising or bleeding; pain or burning during urination;

frequent urination; wound or sore that is red, warm, or won't heal; drainage from a skin wound; general weakness, extreme tiredness, or sick feeling; symptoms of the "flu" or a "cold"; pain or swelling in the neck, groin, or armpits; white patches in the mouth or throat; cold sores; blisters; headache or earache; or other signs of infection.

You may be infected with certain viruses or bacteria but not have any signs of infection. Taking mycophenolate increases the risk that these infections will become more severe and cause symptoms. Tell your doctor if you have any type of infection, such as Hepatitis B or C, including an infection that does not cause symptoms.

Mycophenolate may increase the risk that you will develop progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability). Tell your doctor if you have or have ever had PML, or another condition that affects your immune system such as human immunodeficiency virus (HIV); acquired immunodeficiency syndrome (AIDS); sarcoidosis (a condition that causes swelling in the lungs and sometimes in other parts of the body); leukemia (cancer that causes too many blood cells to be produced and released into the bloodstream); or lymphoma. If you experience any of the following symptoms, call your doctor immediately: weakness on one side of the body or in the legs; difficulty or inability to control your muscles; confusion or difficulty thinking clearly; unsteadiness; memory loss; difficulty speaking or understanding what others say; or a lack of interest or concern for usual activities or things you usually care about.

Mycophenolate may increase your risk of developing certain types of cancer, including lymphoma (a type of cancer that develops in the lymph system) and skin cancer. Tell your doctor if you or anyone in your family has or has ever had skin cancer. Avoid unnecessary or prolonged exposure to real and artificial sunlight (tanning beds, sunlamps) and light therapy and wear protective clothing, sunglasses, and sunscreen (with a SPF factor of 30 or above). This will help to decrease your risk of developing skin cancer. Call your doctor if you experience any of the following symptoms: pain or swelling in the neck, groin, or armpits; a new skin sore or bump; a change in the size or color of a mole; a brown or black skin lesion (sore) with uneven edges or one part of the lesion that does not look like the other; skin changes; sores that do not heal; unexplained fever; tiredness that does not go away; or weight loss.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with mycophenolate and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>] to obtain the Medication Guide.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to mycophenolate.

Talk to your doctor about the risks of taking mycophenolate.

## Why is this medication prescribed?

Mycophenolate (CellCept) is used with other medications to help prevent transplant organ rejection (attack of the transplanted organ by the immune system of the person receiving the organ) in adults who have received heart and liver transplants and in adults and children 3 months of age and older who have received kidney transplants. Mycophenolate (Myfortic) is used with other medications to help prevent the body from rejecting kidney transplants. Mycophenolate is in a class of medications called immunosuppressive agents. It works by weakening the body's immune system so it will not attack and reject the transplanted organ.

## How should this medicine be used?

Mycophenolate comes as a capsule, a tablet, a delayed-release (releases the medication in the intestine) tablet, and a suspension (liquid) to take by mouth. It is usually taken twice a day on an empty stomach (1 hour before or 2 hours after eating or drinking, unless your doctor tells you otherwise). Take mycophenolate at about the same times every day, and try to space your doses about 12 hours apart. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take mycophenolate exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

The medication in the delayed-release tablet (Myfortic) is absorbed differently by the body than the medication in the suspension, tablet, and capsule (CellCept). These products cannot be substituted for each other. Each time you have your prescription filled, make sure that you have received the right product. If you think you received the wrong medication, talk to your doctor and pharmacist right away.

Swallow the tablets, delayed-release tablets, and capsules whole; do not split, chew, or crush them. Do not open the capsules.

Do not mix mycophenolate suspension with any other medication.

Be careful not to spill the suspension or to splash it onto your skin. If you do get the suspension on your skin, wash the area well with soap and water. If you get the suspension in your eyes, rinse with plain water. Use wet paper towels to wipe up any spilled liquids.

Mycophenolate helps prevent organ transplant rejection only as long as you are taking the medication. Continue to take mycophenolate even if you feel well. Do not stop taking mycophenolate without talking to your doctor.

## Other uses for this medicine

Mycophenolate is also used to treat Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever). Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking mycophenolate,

- tell your doctor and pharmacist if you are allergic to mycophenolate, mycophenolic acid, any other medications, or any of the ingredients in the mycophenolate or mycophenolic acid product you are taking. If you are taking mycophenolate liquid, tell your doctor and pharmacist if you are allergic to aspartame or sorbitol. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: activated charcoal; acyclovir (Zovirax); certain antibiotics such as amoxicillin and clavulanic acid (Augmentin), ciprofloxacin (Cipro),, and sulfamethoxazole/trimethoprim (Bactrim); azathioprine (Azasan, Imuran); cholestyramine (Prevalite); ganciclovir (Cytovene, Valcyte); other medications that suppress the immune system; isavuconazonium (Cresemba); probenecid (Probalan); proton pump inhibitors such as lansoprazole (Dexilant, Prevacid) and pantoprazole (Protonix); rifampin (Rifadin, Rimactane, in Rifamate, Rifater); telmisartan (Micardis, in Twynsta); valacyclovir (Valtrex); and valganciclovir (Valcyte). Also tell your doctor if you are taking a combination of both norfloxacin (Noroxin) and metronidazole (Flagyl). Many other medications may also interact with mycophenolate, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Also be sure tell your doctor if you stop taking any of your medications. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are taking sevelamer (Renagel, Renvela), or antacids that contain magnesium or aluminum, take them 2 hours after you take mycophenolate.
- tell your doctor if you have or have ever had Lesch-Nyhan syndrome or Kelley-Seegmiller syndrome (inherited diseases that cause high levels of a certain substance in the blood, joint pain, and problems with motion and behavior); anemia (a lower than normal number of red blood cells); neutropenia (less than normal number of white blood cells); ulcers or any disease that affects your stomach, intestines, or digestive system; any type of cancer; or kidney or liver disease.
- tell your doctor if you are breastfeeding.
- you should know that mycophenolate may make you drowsy, confused, dizzy, lightheaded, or cause uncontrollable shaking of a part of the body. Do not drive a car or operate machinery until you know how this medication affects you.
- do not have any vaccinations without talking to your doctor. Ask your doctor if you should get a flu vaccine before or during your treatment because taking mycophenolate may increase your risk of infection.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that mycophenolate suspension contains aspartame, a source of phenylalanine.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

If you are taking mycophenolate tablet, capsule, or suspension (Cellcept) take the missed dose as soon as you remember it. However, if the next dose is less than 2 hours away, skip the missed dose and

continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you are taking mycophenolate delayed release tablet (Myfortic) take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## **What side effects can this medication cause?**

**Mycophenolate may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- constipation
- stomach pain or swelling
- nausea
- vomiting
- difficulty falling asleep or staying asleep
- pain, especially in the back, muscles, or joints
- headache
- gas
- prickling, tingling, or burning feeling on the skin
- muscle stiffness or weakness

**Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:**

- diarrhea, sudden severe stomach pain
- swelling of the hands, arms, feet, ankles, or lower legs
- difficulty breathing
- chest pain
- rash
- itching
- fast heartbeat
- dizziness
- fainting
- lack of energy
- pale skin
- unusual bleeding or bruising
- black and tarry stools

- red blood in stools
- bloody vomit
- vomit that looks like coffee grounds
- blood in urine
- yellowing of the skin or eyes

Mycophenolate may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Mycophenolate suspension may also be stored in a refrigerator. Do not freeze mycophenolate suspension. Dispose of any unused mycophenolate suspension after 60 days.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- stomach pain
- nausea

- vomiting
- heartburn
- diarrhea
- fever, sore throat, chills, cough and other signs of infection

## What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- CellCept<sup>®</sup>
- Myfortic<sup>®</sup>

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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