

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMYFORTIC®

Mycophenolic acid (as mycophenolate sodium) Enteric-coated Tablets

Read this carefully before you start taking **MYFORTIC®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYFORTIC**.

Serious Warnings and Precautions

- MYFORTIC will only be prescribed for you by a healthcare professional with experience in transplantation medicine.
- **Serious Immune System Problems:** MYFORTIC can have an effect on your immune system, which can lead to death. This can cause:
 - **Blood Problems:** MYFORTIC can cause serious blood problems. This includes; low levels of white blood cells that fight infections (**Leukopenia**), low levels of red blood cells (**Anemia**) and low levels of platelets, the cells that help the blood to clot (**Thrombocytopenia**).
 - **Progressive Multifocal Leukoencephalopathy:** An infection of the brain.
 - **Hepatitis B or C:** If you have had the liver disease hepatitis B or C in the past taking MYFORTIC might make it come back.
 - **Cancer:** MYFORTIC can increase your risk of developing certain types of cancer such as cancer of the lymph nodes (lymphoma) and skin cancer.
 - **Kidney Infection:** A viral infection of the kidneys.See the **Serious side effect and what to do about them** table, below for more information on these and other serious side effects.
- **Pregnancy:** Do **not** take MYFORTIC if you are pregnant. Taking MYFORTIC during pregnancy increases the risk of birth defects and pregnancy loss (miscarriage). If you are a woman who is able to get pregnant you must use two effective forms of birth control at the same time while you are taking MYFORTIC and for six weeks after your last dose.

What is MYFORTIC used for?

MYFORTIC is used in adults to suppress the immune system to prevent your body from rejecting a transplanted kidney.

How does MYFORTIC work?

Your body's immune system works to protect you from infections and other foreign material. When you receive a transplant, your immune system recognizes the new organ as "foreign", and will try to reject it. MYFORTIC works to suppress your immune system, so that your body is more likely to accept the transplanted kidney.

MYFORTIC is used together with other medicines containing cyclosporine and corticosteroids (e.g. prednisone, prednisolone, methyl prednisolone, prednisolone acetate, methyl prednisolone acetate)

which also suppress your immune system. Together these drugs help prevent the rejection of your transplanted kidney.

What are the ingredients in MYFORTIC?

Medicinal ingredient: mycophenolate sodium

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hypromellose phthalate, indigotine (180 mg tablets), iron oxide yellow, iron oxide red (360 mg tablets), lactose anhydrous, magnesium stearate, povidone (K-30), starch and titanium dioxide.

MYFORTIC comes in the following dosage forms:

Enteric-coated Tablets (coated to dissolve only in the intestine): 180 mg and 360 mg

Do not use MYFORTIC if:

- you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium or mycophenolate mofetil or to any of the other ingredients of MYFORTIC.
- you are pregnant, planning to become pregnant or think you may be pregnant. MYFORTIC increases the risk of birth defects and pregnancy loss (miscarriage).
- you are a woman who is able to get pregnant and you are not using effective birth control.
- you are a woman who is able to get pregnant and you have not had two pregnancy tests to show that you are not pregnant.
- you are breast-feeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYFORTIC. Talk about any health conditions or problems you may have, including if you:

- have or have had problems with your stomach (e.g. ulcers caused by the action of stomach acid) or digestive tract (e.g. ulcers, bleeding or perforation);
- need to receive any vaccines (especially live attenuated vaccines such as measles, mumps, rubella (MMR), rotavirus, chickenpox or yellow fever since vaccinations may be less effective during MYFORTIC treatment);
- have a family history of a genetic disease known as Lesch-Nyhan or Kelley-Seegmiller syndrome;
- have problems with your blood, such as low levels of white blood cells (leukopenia) or low levels of red blood cells (anemia).

Other warnings you should know about:

Donating Blood: You must not donate blood while you are taking MYFORTIC and for at least 6 weeks after you stop taking it.

Pregnancy, Birth Control and Breastfeeding:

Female Patients:

- Do **not** get pregnant while you are taking MYFORTIC and for 6 weeks after you stop taking it. MYFORTIC increases the risk of birth defects and pregnancy loss (miscarriage). Tell your healthcare professional immediately if you get pregnant while taking MYFORTIC. You will want to discuss the possible benefits and risks of continuing to take MYFORTIC.

- If you are a woman who is able to get pregnant, you must have two negative blood or urine pregnancy tests before you start taking MYFORTIC. The second test should be done 8-10 days after the first test and immediately before you start taking MYFORTIC. Your healthcare professional will also do pregnancy tests regularly during your treatment with MYFORTIC.
- If you are a woman who is able to get pregnant you must use two effective forms of birth control before you start taking MYFORTIC while you are taking it and for 6 weeks after you stop taking it. Talk to your healthcare professional about the birth control options that are right for you.
- You must **not** breastfeed while you are taking MYFORTIC or for 6 weeks after you stop taking it. MYFORTIC may pass into breast milk and harm your baby.

Male Patients:

- You must **not** father a child while you are taking MYFORTIC or for 90 days after you stop taking it.
- You must use condoms if you are sexually active while you are taking MYFORTIC and for 90 days after you stop taking it.
- If your female partner is able to get pregnant she must use an effective form of birth control while you are taking MYFORTIC and for 90 days after you stop taking it. Tell your healthcare professional immediately if your partner gets pregnant while you are taking MYFORTIC.
- You must not donate sperm/semen while you are taking MYFORTIC and for at least 90 days after you stop taking it.

Cancer Risk: MYFORTIC may increase your risk of developing certain types of cancer including cancer of the lymph nodes (lymphoma) and skin cancer. While you are taking MYFORTIC you should limit your exposure to sunlight and ultraviolet (UV) light by wearing appropriate protective clothing and frequently applying a sunscreen with a high protection factor.

Blood Tests and Monitoring: Be sure to keep all appointments at your transplant clinic. Your healthcare professional will do blood tests and other exams to monitor the levels of your red and white blood cells, the health of your liver and kidneys and to check for other side effects. You will need to have blood tests weekly during the first month, twice monthly for the second and third month of treatment, then monthly through the first year of treatment with MYFORTIC.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYFORTIC:

- Medicines used to suppress the immune system other than cyclosporine or corticosteroids (e.g. azathioprine, mycophenolate mofetil, tacrolimus)
- Cholestyramine, (a medicine used to treat high blood cholesterol levels)
- Acyclovir (a medicine used to treat herpes infection)
- Gancyclovir (a medicine used to treat cytomegalovirus (CMV) infection)
- Antacids (used to treat heartburn)
- Oral birth control (also known as “The Pill”)

How to take MYFORTIC:

- Do not break, crush, chew or cut MYFORTIC tablets. Do not take any tablets that are broken or split. The tablets should be swallowed whole with plenty of water.

- Space your two doses of MYFORTIC as evenly as you can throughout the day leaving about 12 hours between each dose.
- Try to take your doses at the same times each day. This will help keep a constant amount of medicine in your body so it can continue to protect your transplanted kidney. Taking your medicine at the same time each day will also help you remember each dose.
- MYFORTIC should be taken on an empty stomach, one hour before or two hours after food intake.
- Vomiting or diarrhea may prevent MYFORTIC from being taken up into your body. Always call your healthcare professional if you have vomiting or diarrhea.
- Your healthcare professional has decided on the dose of MYFORTIC you should take based on your medical condition and response to the medicine. Follow your healthcare professional's instructions carefully. Do not take any more or any less MYFORTIC than your healthcare professional has told you. Do not change the dose on your own, no matter how you are feeling.
- You will continue taking MYFORTIC for as long as you need immunosuppression to prevent you from rejecting your transplanted kidney.
- Talk to your healthcare professional about how to take your other immunosuppressant medicines while you are taking MYFORTIC.

Usual dose:

Adults: 720 mg twice a day. This means:

-Taking 4 x 180 mg tablets in the morning and 4 x 180 mg tablets in the evening.

OR

-Taking 2 x 360 mg tablets in the morning and 2 x 360 mg tablets in the evening.

Overdose:

If you think you, or a person you are caring for, have taken too much MYFORTIC, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

Missing even a few doses of MYFORTIC may lead to rejection of your transplanted kidney. That is why it is so important to take each dose of MYFORTIC as prescribed.

If you have trouble remembering doses, or if you are uncertain about how to take them talk to your healthcare professional and be sure to discuss any concerns you have about taking MYFORTIC as prescribed.

If you forget to take MYFORTIC, take it as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose; Call your healthcare professional for advice if you are unsure. It is a good idea to ask your healthcare professional ahead of time what to do about missed doses.

Never allow your medication to run out between refills. Plan to order your refills about one week

ahead of time. That way you will always have a supply in case the pharmacy is closed or out of MYFORTIC. Also be sure to take enough medication with you when you go on a holiday.

What are possible side effects from using MYFORTIC?

These are not all the possible side effects you may have when taking MYFORTIC. If you experience any side effects not listed here, tell your healthcare professional.

Some effects could be serious:

If you experience any of the following while you are taking MYFORTIC, talk to your healthcare professional immediately:

- If you experience vision changes, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what others say, and muscle weakness, these can be the signs and symptoms of an infection of the brain called progressive multifocal leukoencephalopathy.
- If you have enlarged glands, new or enlarging skin growths, or a change in an existing mole. As can happen in patients taking immunosuppressive medication a very small number of MYFORTIC patients have developed cancer of the skin or lymph nodes.
- If you have symptoms of infection including fever, chills, sweating, fatigue, drowsiness, or lack of energy. Taking MYFORTIC you may be more susceptible to infections than usual. These may affect various body systems, the most common being the urinary tract, the respiratory tract and the skin.
- If you experience unusual tiredness, headache, shortness of breath with exercise or at rest, dizziness, chest pain, looking pale. These are all symptoms of anemia (low levels of red blood cells).

Other side effects may include:

Very common side effects (> 1 in 10 patients).

- diarrhea
- symptoms of infections including fever, sore throat, chills, sweating, fatigue, drowsiness, or lack of energy (low levels of white blood cells)
- muscle cramps (low levels of calcium in blood)
- muscle weakness, muscle spasms, abnormal heart rhythm (low levels of potassium in the blood)
- joint pain, stiffness, redness and swelling, especially of the big toe (high levels of uric acid in the blood)
- headache, dizziness (symptoms of high blood pressure)
- dizziness, light-headedness (symptoms of low blood pressure)

Common side effects (≤ 10 in every 100 patients).

- muscle cramps, muscle spasms, numbness and tingling in the hands and feet (low levels of magnesium in the blood)
- bleeding or bruising more easily than normal (low levels of blood platelets)
- muscle spasms, abnormal heart rhythm (high levels of potassium in the blood)
- excessive emotional distress, feeling troubled (anxiety)
- dizziness
- headache
- cough

- headache, dizziness, possibly with nausea (severe high blood pressure)
- shortness of breath, trouble breathing
- pain (e.g. in the abdomen, stomach, or joints)
- constipation
- indigestion
- flatulence
- loose stools
- nausea
- vomiting
- tiredness
- fever
- abnormal results of liver or kidney test
- joint pain
- weakness
- muscle pain
- swollen hands, ankles or feet (symptoms of edema)

Uncommon side effects (<1 in 100 patients).

- cyst containing lymph fluid
- trouble sleeping
- shakiness, tremors
- lung congestion
- shortness of breath
- belching, bad breath
- bowel obstruction (inability to pass stool)
- inflammation of the esophagus
- bloody or black stools
- tongue discoloration
- dry mouth
- heartburn; inflammation of the gums
- inflammation of the lining of the abdominal cavity
- flu-like symptoms
- swelling of ankles and feet
- loss of appetite
- hair loss
- bruise of the skin
- acne
- fast heart beat; discharge of the eye with itching, redness and swelling
- blurred vision
- kidney problems (decreased urination, nausea, vomiting, swelling of extremities, fatigue)
- abnormal narrowing of the tube through which urine passes to the outside of the body
- cough, difficulty breathing, painful breathing (symptoms of lung disease including pulmonary fibrosis which can be fatal)

Other side effects with frequency not known

(Frequency cannot be estimated from the available data)

- rash
- Fever, pain in joints, swelling of the joints (acute inflammatory syndrome)

Additional side effects have been reported with the class of drugs to which MYFORTIC belongs.

- Inflammation of the colon or of the esophagus
- abdominal pain
- vomiting
- loss of appetite
- nausea
- inflammation of the pancreas (abdominal pain that lasts and gets worse when you lie down, nausea, vomiting)
- tear in the intestines
- stomach or intestine bleeding
- stomach pain with or without bloody or black stools
- bowel obstruction (inability to pass stool)
- serious infections
- low levels of specific white blood cells or of all blood cells
- fever, sore throat, frequent infections (symptoms of lack of white cells in the blood)

If any of these affects you, tell your healthcare professional. However, do not stop your medicines unless you have discussed this with your healthcare professional first.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Diarrhea	✓		
COMMON			
Bleeding or bruising more easily than normal		✓	
Pain: in the abdomen, stomach, or joints		✓	
Vomiting		✓	
Infections: fever, sore throat, chills, sweating, fatigue, drowsiness, lack of energy		✓	
Urinary tract infection: pain or burning when urinating, strong urge to urinate, cloudy or bloody urine, fever, chills		✓	
UNCOMMON			
Shortness of breath		✓	
Bloody or black stools		✓	
Swelling of ankles and feet		✓	
Palpitation or irregular heart beat		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Viral Infections (cold sores and shingles)		✓	
UNKNOWN			
Severe allergic reactions: rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening and facial/throat swelling			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store MYFORTIC between 15°C to 30°C.

Protect from moisture.

Store in the original package.

Do not use MYFORTIC after the expiry date printed on the container.

Keep out of the reach and sight of children.

If you want more information about MYFORTIC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturers website <http://www.novartis.ca>, or by calling 1-800-363-8883.

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