PART III: CONSUMER INFORMATION

Pr**MYFORTIC®**
Mycophenolic acid enteric-coated tablets 180 mg, 360 mg
(as mycophenolate sodium), Novartis Standard

This leaflet is part III of a three-part "Product Monograph" published when MYFORTIC® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYFORTIC®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for: MYFORTIC is the brand name for a drug called mycophenolate sodium. MYFORTIC belongs to the class of drugs known as immunosuppressants. Immunosuppressants reduce your body's response to anything that it sees as "foreign" – which includes transplant organs.

What it does: MYFORTIC is used to prevent your body from rejecting a transplanted kidney.

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 reduce this reaction, 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.

When it should not be used:

You should not take MYFORTIC if:
- you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium or mycophenolate mofetil or to any of the other ingredients of MYFORTIC (see below).
- you are pregnant or planning to become pregnant or think you may be pregnant as mycophenolate causes birth defects and miscarriage
- you are a woman of childbearing potential not using effective contraception
- you are of childbearing potential and you have not had a pregnancy test to show that you are not pregnant
- you are breast-feeding

If any of the above apply to you, ask your doctor for advice.

What the medicinal ingredient is: MYFORTIC contains mycophenolate sodium, equivalent to 180 mg or 360 mg mycophenolic acid.

What the non-medicinal ingredients are: Colloidal silicon dioxide, crospovidone, lactose anhydrous, magnesium stearate, povidone (K-30), and starch. The enteric coating of the tablet consists of hypromellose phthalate, titanium dioxide, iron oxide yellow, and indigotine (180 mg tablets) or iron oxide red (360 mg tablets).

What dosage forms it comes in: MYFORTIC comes in the form of enteric-coated tablets (coated to dissolve only in the intestine).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- MYFORTIC may increase your risk of infection and development of cancer of the lymphoid tissues (called lymphoma) and other cancers.
- MYFORTIC will only be prescribed for you by a doctor with experience in transplantation medicine.
- Female users of childbearing potential must use contraception. Use of MYFORTIC during pregnancy is associated with increased risks of pregnancy loss and congenital malformations.

Follow your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- For Female Patients:

  - MYFORTIC causes fetal malformations and pregnancy loss including spontaneous abortion. Therefore, MYFORTIC must not be used in pregnant women. Should you become pregnant while on therapy with MYFORTIC, inform your doctor at once. You will want to discuss the possible benefits and risks of continuing with this drug.

  - Women of childbearing potential must have two negative serum (blood) or urine pregnancy tests; the second test, if possible, should be 8-10 days after the first one immediately before starting MYFORTIC.

  Effective contraception must be used before beginning MYFORTIC therapy, during therapy, and for 6 weeks following discontinuation of therapy, even where there has been a history of infertility, unless due to hysterectomy. Two reliable forms of contraception must be used simultaneously unless abstinence is the chosen method. If pregnancy does occur during treatment, the patient should inform the physician immediately, and should discuss the potential risk to the fetus with him/her.

  -MYFORTIC must not be used while breast-feeding, or up to 6 weeks after you have stopped therapy. MYFORTIC may pass into breast milk and may harm your baby.

- MYFORTIC may reduce the effectiveness of vaccinations and the use of live attenuated vaccines should be avoided. Discuss it with your doctor before you get any vaccinations or

immunizations.

If you are a sexually active man, you must use condoms during treatment with MYFORTIC and for 90 days after stopping the treatment. Your partner should also use effective contraception during your treatment and for 90 days after you have stopped MYFORTIC. Tell your doctor straight away if your partner becomes pregnant while you are taking MYFORTIC.

Special precautions to be taken:

- Make sure you know if you are to stop, or to continue, the other immunosuppressant drugs you had been taking. Be sure to discuss this with your doctor.

- Exposure to sunlight should be limited. MYFORTIC reduces your body's defence mechanism, causing an increased risk of skin cancer. You should therefore limit your exposure to sunlight and ultraviolet (or UV) light by wearing appropriate protective clothing and frequently applying a sunscreen with a high protection factor.

- Be sure to keep all appointments at your transplant clinic. During these visits blood tests to determine the number of blood cells you have will need to be conducted weekly during the first month, twice monthly for the second and third month of treatment, then monthly through the first year. In addition, your doctor may order additional blood tests.

- If you already had hepatitis B or C MYFORTIC may increase the risk of these diseases re-appearing. Your doctor may perform blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) you should inform your doctor immediately

BEFORE you use MYFORTIC talk to your doctor or pharmacist:

- if you are pregnant or are planning to become pregnant;

- if you are taking oral contraceptives;

- to ensure that you are using an appropriate method of contraception;

- if you are breast-feeding or plan to breast-feed;

- about all other medical conditions you have now or have had, including problems with your kidneys, stomach (e.g. ulcers caused by the action of stomach acid) or gastrointestinal tract (e.g. ulcers, bleeding, and perforation);

- if you need to receive vaccines (live attenuated vaccines);

- if you have a family history of a genetic disease known as Lesch-Nyhan or Kelley-Seegmiller syndrome;

- if you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium or mycophenolate mofetil or to any of the other ingredients of MYFORTIC;

- if you have any diseases of the blood.

You must not donate blood during treatment with MYFORTIC and for at least 6 weeks after stopping treatment. Men must not donate sperm/semen during treatment with MYFORTIC and for at least 90 days after stopping treatment.

INTERACTIONS WITH THIS MEDICATION

- Tell all health professionals you see (doctors, dentists, nurses, pharmacists) that you are taking MYFORTIC.
- Do not take any other drugs without asking your doctor or pharmacist first. This includes anything you can buy off the shelf such as over-the-counter medicines (e.g. antacids) and natural health products.

Drugs that may interact with MYFORTIC include:
- Immunosuppressive agents 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).
- Non-prescription medications, including antacids or any natural health product.

PROPER USE OF THIS MEDICATION

Usual dose:
The recommended dose in adult is 720 mg administered twice daily. 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.

How it is taken:
- 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 drug in your body so it can

continue to protect your transplanted organ. 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 doctor if you have either of these episodes.

- Your doctor has decided the dose of MYFORTIC you should take based on your medical condition and response to the drug. Follow your doctor's instruction carefully. Do not take any more or any less of the drug than your doctor has told you. Do not change the dose on your own, no matter how you are feeling.

How long is treatment continued:

- Treatment will continue for as long as you need immunosuppression to prevent you from rejecting your transplanted kidney.

Overdose:

In case of drug overdosage, contact a healthcare professional (e.g. doctor), hospital emergency department or regional Poison Control Centre, even if there are no 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 doctor, nurse or pharmacist and be sure to discuss any concerns you have about taking the drug as prescribed.

- If you ever do miss a dose of MYFORTIC, do not double dose or catch up on your own; instead call your doctor or pharmacist right away for advice. It is also a good idea to ask your doctor 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 the drug. Also be sure to take enough medication with you when you go on a holiday.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MYFORTIC can cause side effects, although not everybody gets them.

Some effects could be serious:

- If you have symptoms of infection including fever, chills, sweating, fatigue, drowsiness, or lack of energy. If you are 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 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 experience unusual tiredness, headache, shortness of breath with exercise or at rest, dizziness, chest pain, looking pale. These are all symptoms of anaemia (decrease in red blood cells).

If you experience any of these, tell your doctor straight away.

Other side effects may include:

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

- diarrhea
- low level of white blood cells
- reduced level of calcium in the blood , sometimes leading to cramps, (hypocalcemia)
- muscle weakness, muscle spasms, abnormal heart rhythm (possible symptoms of low level of potassium in the blood) (hypokalemia)
- abnormal blood test results (high level of uric acid in the blood) (hyperuricemia)
- headache, dizziness (possible symptoms of high blood pressure) (hypertension)
- dizziness, light-headedness (possible symptoms of low blood pressure) (hypotension)

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

- bleeding or bruising more easily than normal (signs of low level of blood platelets-thrombocytopenia)
- muscle spasms, abnormal heart rhythm (possible symptoms of high level of potassium in the blood) (hyperkalemia)
- abnormal blood test results (low level of magnesium in the blood) (hypomagnesemia)
- excessive emotional distress, troubled (symptoms of anxiety)
- dizziness
- headache
- cough
- headache, dizziness, possibly with nausea (possible symptoms of severe high blood pressure) (aggravated hypertension)
- shortness of breath, laborated breathing (possible symptoms of dyspnea or dyspnea exertional)

- 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
- pain in join (arthralgia)
- weakness (asthenia)
- muscle pain (myalgia)
- swollen hands, ankles or feet (possible symptoms of edema peripheral)

Uncommon side effects *(<1 in 100 patients).*
- cyst containing lymph fluid
- difficulty in sleeping
- shakiness
- lung congestion
- shortness of breath
- belching;bad breath
- bowel obstruction
- inflammation of the oesophagus
- 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
- vision blurred
- kidney disorders
- abnormal narrowing of the tube through which urine passes to the outside of the body
- cough, difficulty breathing, painful breathing (possible symptoms of interstitial lung disease including fatal pulmonary fibrosis)

Other side effect with frequency not known

(Frequency cannot be estimated from the available data)
- rash
- fever, sore throat, frequent infections (possible symptoms of lack of white cells in the blood) (agranulocytosis)

Additional side effects have been reported with the class of drugs to which MYFORTIC belongs.
- Inflammation of the colon or of the oesophagus
- abdominal pain
- vomiting
- loss of appetite
- nausea
- inflammation of the pancreas
- intestinal perforation
- stomach or intestine bleeding
- stomach pain with or without bloody or black stools
- bowel obstruction
- serious infections
- reduction in the number of specific white blood cells or of all blood cells

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist†
		Only if severe	In all cases	
Very common	Diarrhea	√		
Common	Bleeding or bruising more easily than normal; Pain (e.g. in the abdomen, stomach, or joints); Vomiting; Infections and symptoms of infection (e.g. fever, sore throat); Urinary tract infection		√	
Uncommon	Shortness of breath; Bloody or black stools; Swelling of ankles and feet; Palpitation or irregular heart beat; Viral Infections (cold sores and shingles)		√	

† Do not stop your medicines unless you have discussed this with your doctor first.

This is not a complete list of side effects. For any unexpected effects while taking MYFORTIC, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  -Mail to: Canada Vigilance Program
  Health Canada
  Post Locator 0701C
  Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

• 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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.novartis.ca
or by contacting Novartis at:
1-800-363-8883
Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This leaflet was prepared by
Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd., Dorval, Quebec
H9S 1A9

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