PART III: CONSUMER INFORMATION

MYCOPHENOLATE MOFETIL
mycophenolate mofetil
Capsules and Tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

- MYCOPHENOLATE MOFETIL is used after kidney, heart and liver transplantation to help prevent organ rejection.
- MYCOPHENOLATE MOFETIL belongs to a family of drugs known as "immunosuppressants". These drugs work to "suppress" or reduce the body's immune response.
- MYCOPHENOLATE MOFETIL must be given with other drugs such as cyclosporine (Sandimmune® or Neoral®) and corticosteroids (e.g. prednisone, prednisolone, methylprednisolone, prednisolone acetate, methylprednisolone acetate) which also suppress your immune system. Together these drugs help prevent the rejection of your transplanted organ.

What it does:

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. MYCOPHENOLATE MOFETIL works to reduce this reaction, so that your body is more likely to accept the transplanted organ.

When it should not be used:

- MYCOPHENOLATE MOFETIL should not be used in patients allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or to any component of the drug product (see section titled "What the non-medicinal ingredients are").
- MYCOPHENOLATE MOFETIL should not be used if you are pregnant or breastfeeding.
- MYCOPHENOLATE MOFETIL should not be used if you can become pregnant and are not using highly effective birth control.
- MYCOPHENOLATE MOFETIL should not be used unless you have a pregnancy test result showing that you are not pregnant.

What the medicinal ingredient is:

mycophenolate mofetil

What the non-medicinal ingredients are:

MYCOPHENOLATE MOFETIL 250 mg capsules contain the following non-medicinal ingredients: croscarmellose sodium, starch, magnesium stearate, povidone. The capsule shell contains: red iron oxide, yellow iron oxide, titanium dioxide, gelatin, indigo carmine (FD&C blue #2).

MYCOPHENOLATE MOFETIL 500 mg film-coated tablets contain the following non-medicinal ingredients: microcrystalline cellulose, povidone K 90, talc, croscarmellose sodium, magnesium stearate, opadry purple.

What dosage forms it comes in:

MYCOPHENOLATE MOFETIL 250 mg capsule is available as a blue/orange, imprinted with "SZ" in black colour on cap and "250" in black colour on body, two-piece hard gelatin capsule. They are provided in unit dose of 10 capsules in blister packs, 10 packs per box.

MYCOPHENOLATE MOFETIL 500 mg tablet is available as a lavender coloured, caplet shaped film-coated tablet engraved with "SZ" on one side and "327" on other side. Ten tablets are contained in each blister pack, 5 packs per box and bottles of 100 tablets,

WARNINGS AND PRECAUTIONS

Warning

If you use mycophenolate mofetil in combination with other medicines used to prevent organ rejection when you are pregnant; you are likely to have early pregnancy loss and infant birth defects (see Special Note for Female Patients).

Because mycophenolate mofetil suppresses your immune system, you are more likely to get infections and have a greater chance of developing cancer. The chances of developing either are similar to the chances seen in patients taking other immunosuppressants.

Special Note For Female Patients

- Women must not take MYCOPHENOLATE MOFETIL while they are pregnant as MYCOPHENOLATE MOFETIL may cause an increased risk of first trimester pregnancy loss or damage to the unborn baby (affecting development of ears, limbs, face, heart, brain for example). **For this reason it is recommended that you discuss with your doctor if you are pregnant or become pregnant or plan on becoming pregnant while taking MYCOPHENOLATE MOFETIL.** You will want to discuss the possible benefits and risks of continuing with this drug.
- If you think you may be pregnant tell your doctor straight away. However, keep taking MYCOPHENOLATE MOFETIL until you see him or her.Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.

- Women (who have the potential of becoming pregnant) should have two negative serum (blood) or urine pregnancy tests. The second test should be performed 8-10 days after the first one and immediately before starting MYCOPHENOLATE MOFETIL. You can only start MYCOPHENOLATE MOFETIL if the tests are negative. Repeat pregnancy tests should be performed during routine follow-up visits.
- You must always use two reliable methods of birth control:
    - Before you start taking MYCOPHENOLATE MOFETIL,
    - During your entire treatment with MYCOPHENOLATE MOFETIL and
    - For 6 weeks after stopping your treatment with MYCOPHENOLATE MOFETIL.

  Talk to your doctor about the most suitable methods of contraception for you. This will depend on your individual situation.
- Sexually active men are recommended to use condoms while taking MYCOPHENOLATE MOFETIL and for at least 90 days after stopping treatment.
- If you take oral contraceptives (birth control pills) while using MYCOPHENOLATE MOFETIL you must also use another form of birth control method as MYCOPHENOLATE MOFETIL may adversely affect the efficacy of an oral contraceptive.
- **Do not** breast-feed your baby if you are taking MYCOPHENOLATE MOFETIL as it may pass into breast milk and may harm your baby.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, pregnancy tests may be administered by your doctor.

All Patients

- Tell all health professionals you see (doctor, dentist, nurses, pharmacists) that you are taking MYCOPHENOLATE MOFETIL.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, complete blood counts will need to be measured weekly in the first month, twice monthly for the second and third months of treatment, and then monthly for the remainder of the first year. Your doctor may sometimes order additional blood tests.
- MYCOPHENOLATE MOFETIL reduces your body's defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:
    - wearing protective clothing which also covers your head, neck, arms and legs.
    - using a sunscreen with a high sun protection factor (SPF).

BEFORE you use MYCOPHENOLATE MOFETIL talk to your doctor or pharmacist:

- If you have had a bad, unusual or allergic reaction to MYCOPHENOLATE MOFETIL, mycophenolic acid, or mycophenolate sodium.
- If you are pregnant, plan to become pregnant, are breast-feeding a baby, or plan to breastfeed.
- About all other health conditions you have now or have had in the past, especially problems with your stomach or bowel movements.
- About all other medicines or treatments you have used or are using, including any products you buy at a pharmacy, supermarket or health food store.

INTERACTIONS WITH THIS MEDICATION

- Tell your doctor if you are taking medicines containing telmisartan, rifampicin or azathioprine.
- Do not take any other drugs without asking your doctor or pharmacist first.
- Taking antacids at the same time as MYCOPHENOLATE MOFETIL may affect the way MYCOPHENOLATE MOFETIL works for you and therefore should not be taken simultaneously.
- Taking proton pump inhibitors, such as lansoprazole and pantoprazole, at the same time as mycophenolate may affect the way mycophenolate works for you.
- Taking Renagel® (sevelamer), or other calcium free phosphate binders at the same time as MYCOPHENOLATE MOFETIL may affect the way MYCOPHENOLATE MOFETIL works for you and therefore should not be taken at the same time.
- Taking combinations of antibiotics at the same time as MYCOPHENOLATE MOFETIL may affect the way MYCOPHENOLATE MOFETIL works for you. Do not take any other drugs without asking your doctor or pharmacist first.
- During treatment with MYCOPHENOLATE MOFETIL, vaccinations may be less effective and live vaccines should not be given. **Do** discuss this with your doctor before you get any vaccinations or immunizations.
- Do not take cholestyramine, which is used to treat high blood cholesterol.

PROPER USE OF THIS MEDICATION

- Your doctor has decided the dose you should take based on your medical condition and response to the drug.
- The initial dose of MYCOPHENOLATE MOFETIL should be taken as soon as possible following transplantation. If you are not sure of your dose, or when to take it, ask your doctor, pharmacist or nurse.
- Space your two doses of MYCOPHENOLATE MOFETIL as evenly as you can throughout the day leaving about 12 hours between each dose.
- 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.
- MYCOPHENOLATE MOFETIL must be taken with other immunosuppressive medicines (such as cyclosporine and

corticosteroids). Discuss with your doctor if you are to stop, or to continue, the other immunosuppressant drugs you had been taking.
- Try to take your doses at the same times each day. Taking your medicine at the same time each day will also help you remember each dose.
- Vomiting or diarrhea may prevent MYCOPHENOLATE MOFETIL from being taken up into your body. Always call your doctor if you have either of these episodes.
- **Do not change the dose on your own, no matter how you are feeling. Call your doctor.**
- **Do not stop taking MYCOPHENOLATE MOFETIL on your own even if you have been taking it for several years.**

Usual Dose:
MYCOPHENOLATE MOFETIL should be taken on an empty stomach.

Kidney Transplant Patients
Adults:
- A dose of 1 g taken twice a day (daily dose of 2 g) is recommended after kidney transplantation.

Pediatric Patients:
- Pediatric patients with a body surface area* of 1.25 to 1.5 m^2 may be dosed with MYCOPHENOLATE MOFETIL capsules at a dose of 750 mg twice a day (1.5 g daily dose). Pediatric patients with a body surface area* greater than 1.5 m^2 may be dosed with MYCOPHENOLATE MOFETIL capsules or tablets at a dose of 1 g twice a day (2 g daily dose).

*Body surface area is the total surface area of the body, and is represented as square meters (m^2). It is calculated from your weight and height. Body surface area is used in many measurements in medicine, such as determining the amount of drug you need to take.

Heart Transplant Patients
Adults:
- A dose of 1.5 g twice a day (daily dose of 3 g) is recommended after heart transplantation in adults.

Liver Transplant Patients
Adults:
- A dose of 1.5 g taken twice a day (daily dose of 3 g) is recommended after liver transplantation in adults.

How Do I Take MYCOPHENOLATE MOFETIL?
It is important to leave the capsules or tablets in the blister pack/bottle until you need a dose. When you are ready to take a dose, remove the number of capsules or tablets you need to make up the dose your doctor prescribed. **Swallow the capsule or tablets whole** with plenty of water; **do not crush them**. Avoid contact with any powder, including accidental inhalation, from damaged capsules or tablets. Wash any powder from your skin with soap and water; rinse eyes with plain water.

Woman of childbearing age should not touch this medication with bare hands. Use gloves. See additional information under Warnings and Precautions, Special Note For Female Patients.

Pharmacist: Dispense with complete instructions to the patient as given under Consumer Information. It is recommended that this medication should be dispensed in a tightly closed container preferably in the original packaging.

Overdose:

If you think you have taken too much MYCOPHENOLATE MOFETIL, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
- 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.
- If you ever do miss a dose of MYCOPHENOLATE MOFETIL, do **not** 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. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Like all medicines, along with the beneficial effects of treatment, MYCOPHENOLATE MOFETIL may cause side effects in people.
- Because MYCOPHENOLATE MOFETIL and the other medicines to be taken suppress your immune system, you are more likely to get infections. To help reduce complications from infections, tell your doctor about any cold or flu-like symptoms (such as fever or sore throat), any boils on your skin, or pain when you urinate (pass your water).
- The following symptoms are some possible warning signs of cancer. To help detect any cancers as soon as possible, report any of these symptoms to your doctor right away:
  - a change in your bowel or bladder habits;
  - any sore that doesn't heal;
  - unusual bleeding or discharge;
  - the appearance of a lump or thickened areas in your breast or anywhere else on your body;
  - unexplained stomach upset or any trouble with swallowing;
  - an obvious change in a wart or a mole;
  - a nagging cough or hoarseness;
  - night sweats;
  - persistent and severe headaches.
- Patients taking MYCOPHENOLATE MOFETIL in combination therapy with cyclosporine and corticosteroids may experience an increase in blood pressure.

- Serious common and uncommon side effects which have been reported with MYCOPHENOLATE MOFETIL when used in combination with cyclosporine and corticosteroids, are provided in the following table. Tell your doctor right away if you notice any of these symptoms. Do not stop taking this drug on your own.

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	
Common	Abdominal, chest, or back pain; Blood in urine; Constipation; Diarrhea; Fever; Headache; Heart burn; Laboured breathing; Nausea; Nosebleed; Swelling of parts of your body; Vomiting; Weakness		✓	
Uncommon	Blood or black tarry stools; Dizziness; Increased cough; Involuntary trembling; Sleeplessness; Stomach pain		✓	

†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 you have while taking MYCOPHENOLATE MOFETIL, contact your doctor or pharmacist.

HOW TO STORE IT

- **Keep MYCOPHENOLATE MOFETIL out of reach and sight of children.** A child who accidentally takes the drug may be seriously harmed. A locked drawer or cupboard is best if you have small children in the house.
- MYCOPHENOLATE MOFETIL should be stored between 15 and 30ºC. The capsules or tablets should be protected from light. **Remember to keep each capsule or tablet in its original package until you need to take it.**
- MYCOPHENOLATE MOFETIL should not be used after the expiry date (EXP) shown on the package.

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
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction 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.

MORE INFORMATION

This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sanis Health Inc., at:
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Last revised: May 5, 2017