

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MAR-MYCOPHENOLATE MOFETIL**

mycophenolate mofetil

Powder for Oral Suspension

Read this carefully before you start taking **MAR-MYCOPHENOLATE MOFETIL** 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 **MAR-MYCOPHENOLATE MOFETIL**.

Serious Warnings and Precautions

- MAR-MYCOPHENOLATE MOFETIL can cause **first trimester pregnancy loss (miscarriage) and birth defects** when used along with other medicines used to prevent organ rejection. You must not take MAR-MYCOPHENOLATE MOFETIL if you are pregnant. Taking MAR-MYCOPHENOLATE MOFETIL while pregnant can harm your unborn baby. Women must have two negative pregnancy tests before starting treatment with MAR-MYCOPHENOLATE MOFETIL. Women must use two reliable forms of contraception at the same time while taking MAR-MYCOPHENOLATE MOFETIL. See “Other warnings you should know about, Important warnings for women taking MAR-MYCOPHENOLATE MOFETIL” for more information.
- MAR-MYCOPHENOLATE MOFETIL **suppresses your immune system**. This can make you more likely to get **infections** and certain **cancers**, such as lymphoma. See “Other warnings you should know about, Serious infections and cancer” for more information.
- MAR-MYCOPHENOLATE MOFETIL will be prescribed to you by a doctor with experience in medicines used to prevent organ rejection.

What is MAR-MYCOPHENOLATE MOFETIL used for?

- MAR-MYCOPHENOLATE MOFETIL is used after kidney, heart and liver transplantation to help prevent organ rejection.
- It is used along with other medicines including cyclosporine and medicines called corticosteroids.

How does MAR-MYCOPHENOLATE MOFETIL work?

MAR-MYCOPHENOLATE MOFETIL works by slowing down your body's defense system (immune system). When you receive an organ transplant, mycophenolate mofetil prevents your body from rejecting this organ.

What are the ingredients in MAR-MYCOPHENOLATE MOFETIL?

Medicinal ingredients: mycophenolate mofetil

Non-medicinal ingredients:

MAR-MYCOPHENOLATE MOFETIL 200 mg/mL powder for oral suspension contains the following non-medicinal ingredients: aspartame, citric acid anhydrous, colloidal silicon dioxide, powderome mixed fruit premium, methylparaben, tri-sodium citrate dihydrate, sorbitol, soybean lecithin, and xanthan gum.

MAR-MYCOPHENOLATE MOFETIL comes in the following dosage forms:

As a powder for suspension containing 200 mg/mL mycophenolate mofetil.

Do not use MAR-MYCOPHENOLATE MOFETIL if you:

- are allergic to mycophenolate mofetil or to mycophenolic acid.
- are allergic to any other ingredients in MAR-MYCOPHENOLATE MOFETIL.
- are pregnant.
- are breastfeeding.
- are of childbearing age and not using highly effective birth control.
- do not have results from a pregnancy test showing that you are not pregnant.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MAR-MYCOPHENOLATE MOFETIL. Talk about any health conditions or problems:

- If you are already on any immune suppressant treatment.
- Rare diseases called Lesch-Nyhan and Kelley-Seegmiller syndrome.
- Digestive problems, including ones with your stomach or bowels.
- Severe renal problems.

Other warnings you should know about:

Important warnings for women taking MAR-MYCOPHENOLATE MOFETIL

- Do not take MAR-MYCOPHENOLATE MOFETIL if you are pregnant.
- MAR-MYCOPHENOLATE MOFETIL can cause first trimester pregnancy loss (miscarriage) and birth defects when used along with other medicines used to prevent organ rejection.
- These birth defects can affect the development of a baby's ears, limbs, face, heart and brain.
- You can only take MAR-MYCOPHENOLATE MOFETIL if you are not pregnant and if you are using highly effective birth control.
- If you think you may be pregnant tell your doctor right away. Keep taking MAR-MYCOPHENOLATE MOFETIL until you see your doctor. They will talk to you about other medicines you can take to prevent rejection of your transplanted organ.
- Women who can get pregnant must have two negative blood or urine pregnancy tests. The second test should be performed 8-10 days after the first. You can only start MAR-MYCOPHENOLATE MOFETIL if the tests are negative. You will be given repeat pregnancy tests during follow-up visits.
- You must always use two reliable methods of birth control:
- Before you start taking MAR-MYCOPHENOLATE MOFETIL,
- During your entire treatment with MAR-MYCOPHENOLATE MOFETIL and
- For 6 weeks after stopping your treatment with MAR-MYCOPHENOLATE MOFETIL.
- Talk to your doctor about the best methods of contraception for you. If you take oral contraceptives (birth control pills) while using MAR-MYCOPHENOLATE MOFETIL you must also use another form of birth control

method. This is because MAR-MYCOPHENOLATE MOFETIL may make oral contraceptives less effective.

Important warnings for men taking MAR-MYCOPHENOLATE MOFETIL

- If you are a sexually active male, you must use effective birth control. Or, your female partner must use effective birth control while you are taking MAR-MYCOPHENOLATE MOFETIL. Effective birth control must be used for at least 90 days after you stop taking MAR-MYCOPHENOLATE MOFETIL. Men should not donate semen during therapy and for 90 days after taking of MAR-MYCOPHENOLATE MOFETIL.

Serious infections and cancers:

- MAR-MYCOPHENOLATE MOFETIL suppresses your immune system. This can make you more likely to get infections and certain cancers, such as lymphoma and skin cancer.
- MAR-MYCOPHENOLATE MOFETIL slows down your immune system. This can affect your body's ability to fight infections. You are more likely to get infections when you take MAR-MYCOPHENOLATE MOFETIL. Some of these infections can be serious and fatal. Infections include: viral infections, a brain infection called progressive multifocal leukoencephalopathy, sepsis and other infections. It can also cause other infections to emerge in your body like hepatitis B or C or infections caused by polyomaviruses. See "Serious side effects and what to do about them" table for more information.
- MAR-MYCOPHENOLATE MOFETIL increases your chances of getting certain cancers, especially skin cancers. See "Serious side effects and what to do about them" table for more information. You must 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).

Additional important warnings for all patients taking MAR-MYCOPHENOLATE MOFETIL:

- Tell all health professionals you see that you are taking MAR-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.
- You should not donate blood during therapy and for at least 6 weeks after taking MAR-MYCOPHENOLATE MOFETIL.
- During treatment with MAR-MYCOPHENOLATE MOFETIL, vaccinations may be less effective. Also, you should not receive vaccines. Talk to your doctor before receiving any vaccines.

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 MAR-MYCOPHENOLATE MOFETIL:

- Acyclovir, an antiviral medication;
- Ganciclovir or valganciclovir, antiviral medications'
- Isavuconazole, an antiviral medication;
- Tacrolimus, used to suppress the body's immune system;
- Telmisartan, used to treat high blood pressure;
- Rifampicin, an antibiotic;

- Azathioprine, used to suppress the body's immune system;
- Antacids, which neutralize stomach acidity;
- Proton pump inhibitors, such as lansoprazole and pantoprazole;
- Renagel® (sevelamer), or other calcium free phosphate binders;
- Cholestyramine, which is used to treat high blood cholesterol.
- Combinations of antibiotics taken at the same time.

How to take MAR-MYCOPHENOLATE MOFETIL:

- Take MAR-MYCOPHENOLATE MOFETIL exactly as your doctor has told you to. Ask your healthcare professional if you are not sure.
- Your initial dose of MAR-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.
- Take MAR-MYCOPHENOLATE MOFETIL on an empty stomach.
- Space your two doses of MAR-MYCOPHENOLATE MOFETIL as evenly as you can throughout the day leaving about 12 hours between each dose.
- Take MAR-MYCOPHENOLATE MOFETIL along with other medicines prescribed to you, including cyclosporine and medicines called corticosteroids. These are also medicines used to prevent rejection of your transplanted organ. It is important to take all of these medicines properly. Talk to your doctor if you are not sure.
- 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 MAR-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 MAR-MYCOPHENOLATE MOFETIL on your own even if you have been taking it for several years.**

Usual dose:

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:

- Your doctor will decide how much MAR-MYCOPHENOLATE MOFETIL you will receive. The dose will depend on your body surface area.

Heart Transplant PatientsAdults:

- 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:

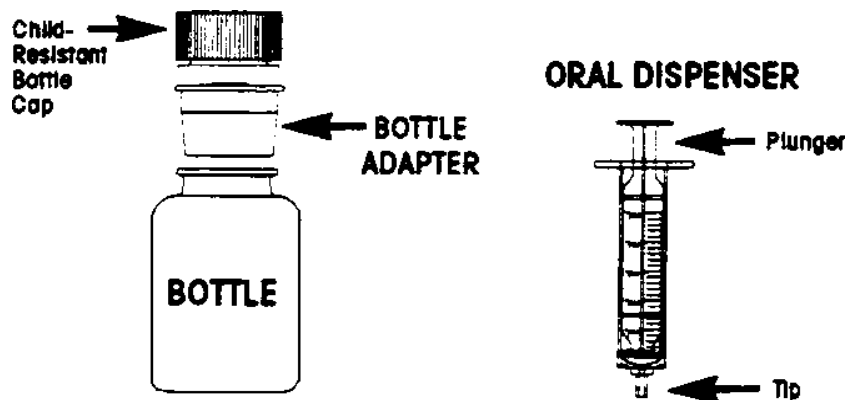
- A dose of 1.5 g taken twice a day (daily dose of 3 g) is recommended after liver transplantation in

adults.

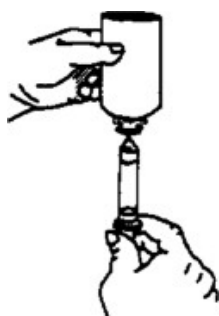
How Do I Take MAR-MYCOPHENOLATE MOFETIL?

Oral Suspension:

- Please follow instructions carefully to ensure proper dosing of the oral suspension.



1. Put on disposable gloves.
2. Shake closed bottle well for about 5 seconds before each use.
3. Remove the child-resistant cap (see figure above).
4. Before inserting the tip of the dispenser into bottle adapter, push the plunger completely down toward the tip of the dispenser. Insert tip firmly into opening of the bottle adapter.
5. Turn the entire unit (bottle and dispenser) upside down.
6. Pull the plunger out slowly until the desired amount of medication is withdrawn into the dispenser (see figure below).
7. Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.



8. Dispense directly into mouth. Do not mix with any liquid prior to dispensing.
9. Close bottle with child-resistant cap after each use.
10. Disassemble oral dispenser, rinse under running tap water and air dry prior to next use.

- Avoid contact of the skin and eyes with both the oral suspension powder and the mixed suspension. In case of contact with the eyes, rinse with water. In case of contact with skin, wash thoroughly with soap and water.
- Wipe up any spills using wet paper towels. Recap the bottle and wet wipe its outside surfaces.
- Be sure you are wearing disposable gloves when wiping any spills.

Overdose:

If you think you, or a person you are caring for, have taken too much MAR-MYCOPHENOLATE MOFETIL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you ever do miss a dose of MAR-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.

What are possible side effects from using MAR-MYCOPHENOLATE MOFETIL?

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

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		√	
Abdominal pain		√	
Blood in urine		√	
Constipation		√	
Increased cough		√	
Diarrhea		√	
Fever		√	
Laboured breathing		√	
Headache		√	
High blood pressure		√	
Swelling of parts of your body		√	
Vomiting		√	
Weakness		√	
COMMON			
Chest or back pain		√	
Dizziness		√	
Heart burn		√	
Involuntary trembling		√	

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	
Muscle weakness		√	
Nausea		√	
Nosebleed		√	
Sleeplessness		√	
Stomach pain		√	
Sepsis (severe infection): fever and chills, low body temperature, fast heartbeat, nausea and vomiting		√	
Gastrointestinal perforation (a hole in your stomach or bowels): chills or fever, nausea, severe abdominal pain, vomiting		√	
RARE			
Blood or black tarry stools		√	
UNKNOWN			
Progressive multifocal leukoencephalopathy (infection of the brain): loss of coordination, difficulty walking, facial drooping, loss of vision, trouble speaking		√	
Infections: body aches and pains, boils on your skin, chills, cold symptoms, earache, flu-like symptoms, headache, pain when you urinate, sore throat, cuts and scrapes that are red, have pus or don't heal.		√	
Pure red cell aplasia (bone marrow stops producing red cells): dizziness, fainting, fatigue, feeling unwell, pale skin, pale stools, rapid heartbeat, shortness of breath, weakness		√	
Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms.		√	
Bone marrow suppression (a large decrease in the production of blood cells and platelets by the		√	

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	
bone marrow): fatigue, increased heart rate, unexpected bruising, bleeding; paleness of the skin, lips, and nail beds; dizziness			
BK virus-associated nephropathy (kidney disease due to an infection): changes in vision, like blurred vision; changes in the color of your urine (urine that is brown or red in color); difficulty urinating; needing to urinate more than is normal for you; a cough, cold, or trouble breathing; fever, muscle pain, or weakness		√	
Certain types of cancers (such as lymphoma and skin cancer): new moles, skin lesions or bumps; change in the size or colour of a mole, moles with uneven borders or that are asymmetric, fever, prolonged tiredness, weight loss, lymph node swelling, a change in your bowel or bladder habits, 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, a nagging cough or hoarseness, night sweats		√	

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 HealthCanada by:

- Visiting the Web page on Adverse Reaction Reporting <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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:

- **Keep MAR-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.
- MAR-MYCOPHENOLATE MOFETIL suspension should be stored at room temperature (15-30°C). Do not freeze. The pharmacist will write the date of expiration on the bottle label.
- MAR-MYCOPHENOLATE MOFETIL should not be used after the expiry date (EXP) shown on the package.

If you want more information about MAR-MYCOPHENOLATE MOFETIL:

- 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 manufacturer's website [www.marcanpharma.com], or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc.

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