

**MYNOFTIL** 500mg Tablets  
**Mycophenolate Mofetil**

مائی نوفٹیل  
کولیج (مائی کوفنولیت موفٹیل)

**Composition:**

**Mynofetil 500mg Tablet:**

Each film coated tablet contains:  
Mycophenolate Mofetil .....500mg.  
(USP Specs.)

**WARNING:**

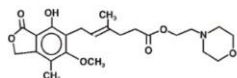
Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use Mynofetil. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Female users of childbearing potential must use contraception. Use of Mynofetil during pregnancy is associated with increased risk of pregnancy loss and congenital malformations.

**Description:**

Mynofetil (mycophenolate) is the 2 morpholinoethyl ester of mycophenolic acid (MPA), an immunosuppressive agent; inosine monophosphate dehydrogenase (IMPDH) inhibitor.

The chemical name for mycophenolate mofetil (MMF) is 2- morpholinoethyl (E)-6- (1,3 dihydro-4-hydroxy-7-methyl-3-oxo-5 isobenzofuranyl) -4-methyl-4 hexenoate. It has an empirical formula of C<sub>23</sub>H<sub>31</sub> N O<sub>7</sub>, a molecular weight of 433.50, and the following structural formula;



**Indication & Usage:**

Mycophenolate is used in combination with other medications to keep your body from attacking and rejecting your transplanted organ (such as kidney, liver, heart). It belongs to a class of medications called immunosuppressants. It works by weakening your body's defense system (immune system) to help your body accept the new organ as if it were your own.

**Dosage & Administration:**

Read the Medication Guide provided by your doctor before you start taking mycophenolate and each time you get a refill. If you have any questions, ask your doctor.

Take this medication by mouth as directed by your doctor.

Swallow the medication whole. Do not crush or chew.

Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the tablets.

The dosage is based on your medical condition and response to treatment. In children, it is also based on body size.

Use this medication regularly to get the most benefit from it. To help you remember, take it at the same times each day.

It is very important to continue taking this medication even if you feel well. Do not stop taking mycophenolate without first talking to your doctor.

Certain products may make it harder for your body to absorb mycophenolate if they are taken at the same time. Do not take this medication at the same time as antacids containing aluminum and/or magnesium, cholestyramine, colestipol, or calcium-free phosphate binders (such as aluminum products, lanthanum, sevelamer). Ask your doctor for more details.

Do not change brands or forms of mycophenolate unless directed by your doctor.

**How much to take:**

The amount you take depend on the type of transplant you have had. There commended doses are shown below. Treatment will continue for a long as you need to prevent you from rejecting your transplant organ.

**Kidney transplant:**

**Adults:**

- The first dose is given with in 3 days of the transplant operation.
- The daily dose is 4 tablets (2g of the medicine) taken as 2 separate doses.
- Take 2 tablets in the morning and then 2 tablets in the evening.

**Children and adolescents (aged 2 to 18 years)**

- The dose given will vary depending on the size of the child.
- Your doctor will decide the most appropriate dose based on your child's height and weight (body surface area – measured as squaremetres or m<sup>2</sup>). The recommended dose is 600mg/m<sup>2</sup> taken twice a day.

Mycophenolate mofetil tablets are not recommended for kidney transplant patients under 2 years of age.

**Heart transplant:**

**Adults**

- The first dose is given with in 5 days of the transplant operation.
- The daily dose is 6 tablets (3g of the medicine) taken as 2 separate doses.
- Take 3 tablets in the morning and then 3 tablets in the evening.

**Children and adolescents:**

- There is no information for the use of Mycophenolate mofetil tablets in children

with a heart transplant.

**Liver transplant:**

**Adults**

- The first dose of oral Mycophenolate mofetil tablets will be given to you at least 4 days after the transplant operation and when you are able to take oral medicines.
- The daily dose is 6 tablets (3g of the medicine) taken as 2 separate doses.

- Take 3 tablets in the morning and then 3 tablets in the evening.

**Children and adolescents**

- There is no information for the use of Mycophenolate mofetil tablets in children with a liver transplant.

**If you take more Mycophenolate mofetil tablets than you should:**

If you take more Mycophenolate mofetil tablets than you should, talk to a doctor or go to a hospital straight away.

Also do this if someone else accidentally takes your medicine. Take the medicine pack with you. **If you forget to take Mycophenolate mofetil tablets:**

If you forget to take your medicine at any time, take it as soon as you remember. Then continue to take it at the usual times.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Mycophenolate mofetil tablets:**

Do not stop taking Mycophenolate mofetil tablets unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your transplanted organ.

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

**Warning & Precautions:**

Before taking mycophenolate mofetil, tell your doctor if you are allergic to it; or to mycophenolic acid; or to mycophenolate sodium; or if you have any other allergies.

This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your doctor for more details.

Before using this medication, tell your doctor your medical history, especially of: cancer, liver disease (such as hepatitis B, hepatitis C), kidney disease, current/past infections (such as herpes, shingles), stomach/intestinal problems (such as ulcers), rare genetic disorders (such as Lesch-Nyhan or Kelley-Seegmiller syndromes).

Do not donate blood while using mycophenolate and for 6 weeks after stopping this drug. Do not donate sperm while using mycophenolate and for 90 days after stopping this drug.

It is unknown if this drug passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

**Drug Interactions:**

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: other drugs that weaken the immune system/increase the risk of infection (such as natalizumab, rituximab).

This medication may decrease the effectiveness of hormonal birth control such as pills, patch, or ring. This could cause pregnancy. If you are using hormonal birth control, you should use an additional non-hormonal form of birth control while using this medication. Discuss your options with your doctor. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

**Overdose:**

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, discuss your options with your doctor.

**MEDICATION GUIDE:**

**What is the most important information I should know about Mynofetil ?**

**Mynofetil can cause serious side effects:**

**Possible loss of a pregnancy and higher risk of birth defects.**

Women who take Mynofetil during pregnancy have a higher risk of losing a pregnancy (miscarriage) during the first 3 months (first trimester), and a higher risk that their baby will be born with birth defects.

If you are a female and are able to become pregnant

-your healthcare provider must talk with you about effective birth control methods (contraceptive counseling)

-you should have a negative pregnancy test within 1 week before you start to take Mynofetil

-you must use 2 different types of effective birth control at the same time, for 4 weeks before you start taking Mynofetil, during your entire Mynofetil therapy and for 6 weeks after stopping Mynofetil, unless you choose to avoid sexual intercourse completely (abstinence). Mynofetil decreases blood levels of the hormones in birth control pills that you take by mouth. Birth control pills may not work as well while you take Mynofetil, and you could become pregnant.

If you plan to become pregnant, talk with your healthcare provider. Your healthcare provider will decide if other medicines to prevent rejection may be right for you. In certain situations, you and your healthcare provider may decide that taking Mynofetil is more important to your health than the possible risks to your unborn baby.

**Increased risk of getting serious infections.** Mynofetil weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with Mynofetil and can lead to death. Types of infections can include:

**Viral infections.** Viral infections, including shingles, other herpes infections, and cytomegalovirus (CMV), can happen with Mynofetil. CMV can cause serious tissue and blood infections.

**A brain infection called Progressive Multifocal Leukoencephalopathy (PML).**

In some patients, Mynofetil may cause an infection of the brain that may cause death. You are at risk for this brain infection because you have a weakened immune system. You should tell your healthcare provider right away if you have any of the following symptoms:

- Weakness on one side of the body
- You do not care about things that you usually care about (apathy)
- You are confused or have problems thinking
- You can not control your muscles.

#### Fungal infections.

Yeasts and other types of fungal infections can happen with Mynofitil and can cause serious tissue and blood infections (see ”)

#### Call your doctor if you have any of the following signs and symptoms of infection:

- Temperature of 100.5°F or greater
- Cold symptoms, such as a runny nose or sore throat
- Flu symptoms, such as an upset stomach, stomach pain, vomiting or diarrhea
- Earache or headache
- Pain during urination
- White patches in the mouth or throat
- Unexpected bruising or bleeding
- Cuts, scrapes or incisions that are red, warm and oozingpus.

#### Increased risk of getting certain cancers.

People who take Mynofitil have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your healthcare provider if you have:

- unexplained fever, prolonged tiredness, weight loss or lymph node swelling
- a brown or black skin lesion with uneven borders, or one part of the lesion does not look like the other.
- a change in the size and color of a mole
- a new skin lesion or bump
- any other changes to your health

#### Who should not take Mynofitil ?

**Do not take Mynofitil if you are allergic to mycophenolate mofetil or any of the ingredients in Mynofitil .** See the end of this Medication Guide for a complete list of ingredients in Mynofitil .

#### What should I tell my healthcare provider before taking Mynofitil ?

Tell your healthcare provider about all of your medical conditions, if you:

- have any **digestive problems**, such as ulcers
- have **Lesch-Nyhan or Kelley-Seegmiller syndrome or another rare inherited deficiency hypoxanthine-guanine phosphoribosyl-transferase (HGPRT)**. You should not take Mynofitil if you have one of these disorders
- plan to receive any vaccines. People taking Mynofitil should not take live vaccines.** Some vaccines may not work as well during treatment with Mynofitil.
- are breastfeeding.** It is not known if Mynofitil passes into breast milk. You and your healthcare provider will decide if you will take Mynofitil or breastfeed. You should not do both without first talking with your healthcare provider.

**Tell your healthcare provider about all of the medicines you are taking including prescription and nonprescription medicines, vitamins and herbal supplements.** Some medicines may affect the way Mynofitil works, and Mynofitil may affect how some medicines work. Especially tell your healthcare provider if you take:

These products should be taken 2 hours after taking Mynofitil valacyclovir, ganciclovir, valganciclovir,

- rifampin
- sulfamethoxazole / trimethoprim.
- norfloxacin and metronidazole
- ciprofloxacin and amoxicillin plus clavulanic acid
- azathioprine
- cholestyramine

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine. Do not take any new medicine without talking with your health care provider.

#### How should I take Mynofitil ?

- Take Mynofitil exactly as prescribed.
- Do not stop taking Mynofitil or change the dose unless your healthcare provider tells you to
- If you miss a dose of Mynofitil , or are not sure when you took your last dose, take the regular amount of Mynofitil prescribed as soon as you remember. If it is time for your next dose, skip the missed dose. Do not take 2 doses at the same time. Call your healthcare provider if you are not sure what to do
- Take Mynofitil capsules, tablets and oral suspension on an empty stomach, either 1 hour before or 2 hours after a meal, unless your healthcare provider tells you otherwise. With the approval of your healthcare provider, in stable kidney transplant patients, Mynofitil can be taken with food if necessary.
- Most people take Mynofitil by mouth either as blue and brown capsules or lavender tablets. Some people may get Mynofitil soon after their transplant surgery as an infusion into a vein.
- Do not crush Mynofitil tablets.
- If you are not able to swallow Mynofitil tablets. This is a liquid form of Mynofitil . Your pharmacist will mix the medicine before giving it to you
- If you take too much Mynofitil , call your healthcare provider or the poison control center right away

#### What should I avoid while taking Mynofitil ?

##### Limit the amount of time you spend in sunlight.

Avoid using tanning beds or sunlamps. People who take Mynofitil have a higher risk of getting skin cancer. (See ”) Wear protective clothing when you are in the sun and use a sun screen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer

#### What are the possible side effects of Mynofitil?

##### Mynofitil can cause serious side effects:

##### Low blood cell counts.

People taking high doses of Mynofitil each day may have a decrease in blood counts, including.

##### white blood cells, especially neutrophils.

Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white blood cell count is low. This is most common from 3 months to 6 months after your transplant.

##### Red blood cells.

Red blood cells carry oxygen to your body tissues. You have a higher chance of getting severe anemia when your red blood cell count is low

##### platelets.

Platelets help with blood clotting Your healthcare provider will do blood tests before you start taking Mynofitil and during treatment with Mynofitil to check your blood cell counts.

Tell your healthcare provider right away if you have any signs of infection (see ”), or any unexpected bruising or bleeding. Also, tell your healthcare provider if you have unusual tiredness, lack of energy, dizziness or fainting.

##### Stomach problems.

Stomach and intestinal bleeding can happen in people who take high doses of Mynofitil . Bleeding can be severe and you may have to be hospitalized for treatment

##### Common side effects include:

·diarrhea. Call your healthcare provider right away if you have diarrhea. Do not stop taking Mynofitil without first talking with your health care provider

- vomiting
- pain
- stomach area pain
- swelling of the lower legs, ankles and feet
- high blood pressure

Side effects that happen more often in children than in adults taking Mynofitil include:

- stomach area pain
- sore throat
- fever
- colds (respiratory tract infections)
- infection
- high blood pressure
- pain- low white blood cell count
- blood infection (sepsis)
- low red blood cell count
- diarrhea
- vomiting

These are not all of the possible side effects of Mynofitil . Tell your healthcare provider about any side effect that bothers you or that does not go away.

##### Storage:

Protect from heat, light and moisture.  
All Medicine should be kept out of the reach of children.  
Store below 30°C.

##### Presentation:

Mynofitil 500mg tablet is available in 40's pack.

خوراک :-  
ڈاکٹر کی ہدایت کے مطابق استعمال کریں ۔  
چاہیات :-  
روشنی نمی اور گرمی سے بچائیں ۔  
تمام ادویات بچوں کی پہنچ سے دور رکھیں ۔  
دوا کو 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں ۔



Manufactured by:  
**GENOME PHARMACEUTICALS (PVT.) LTD.**  
Plot # 16/1, Phase IV, Industrial Estate Hattar-Pakistan.



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