

Package leaflet: Information for the patient

Mycophenolate mofetil 1 g/5 ml powder for oral suspension

Mycophenolate mofetil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Mycophenolate mofetil is and what it is used for
2. What you need to know before you take Mycophenolate mofetil
3. How to take Mycophenolate mofetil
4. Possible side effects
5. How to store Mycophenolate mofetil
6. Contents of the pack and other information

1. What Mycophenolate mofetil is and what it is used for

Mycophenolate mofetil contains mycophenolate mofetil which belongs to a group of medicines called “immuno-suppressants”.

Mycophenolate mofetil is used to prevent your body rejecting a transplanted organ, a kidney, heart, or liver.

Mycophenolate mofetil should be used together with other medicines: cyclosporin and corticosteroids.

2. What you need to know before you take Mycophenolate mofetil

WARNING

Mycophenolate causes birth defects and miscarriage. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor.

Your doctor will speak to you and give you written information, particularly on the effects of mycophenolate on unborn babies. Read the information carefully and follow the instructions.

If you do not fully understand these instructions, please ask your doctor to explain them again before you take mycophenolate. See also further information in this section under “Warnings and precautions” and “Pregnancy and breast-feeding”.

Do not take Mycophenolate mofetil:

- If you are allergic to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor straight away before starting treatment with Mycophenolate mofetil:

- If you are older than 65 years as you may have an increased risk of developing adverse events such as certain viral infections, gastrointestinal bleeding and pulmonary oedema when compared to younger patients
- If you have a sign of infection such as a fever or sore throat
- If you have any unexpected bruising or bleeding
- If you have ever had a problem with your digestive system such as a stomach ulcer
- If you have a rare problem with your metabolism called “phenylketonuria” which runs in families
- If you are planning to become pregnant or if you get pregnant while you or your partner are taking Mycophenolate mofetil.
- If you have a hereditary enzyme deficiency such as Lesch-Nyhan and Kelley-Seegmiller syndrome
- If you are breast-feeding.
- If you plan to receive vaccination
- If you are going to donate blood, as you must not donate blood during treatment with mycophenolate mofetil and for at least 6 weeks after stopping treatment.
- If you are going to donate semen, you must not donate blood during treatment with mycophenolate mofetil and for at least 90 days after stopping treatment.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Mycophenolate mofetil.

The effect of sunlight

Mycophenolate mofetil reduces your body’s defenses. As a result, there is an increased risk of skin cancer. This is especially important if your skin is very fair or if you have a family history of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:

- wearing protective clothing that covers your head, neck, arms, and legs
- using a sunscreen with a high protection factor.
- Avoiding the use of tanning beds or sunlamps

Children

This medicine can be used for children 3 months of age and older.

Other medicines and Mycophenolate mofetil:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, such as herbal medicines. This is because Mycophenolate mofetil can affect the way some other medicines work. Also, other medicines can affect the way Mycophenolate mofetil works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Mycophenolate mofetil:

- azathioprine or other medicines that suppress your immune system - given after a transplant operation

- cholestyramine - used to treat high cholesterol
- rifampicin - an antibiotic used to prevent and treat infections such as tuberculosis (TB)
- proton pump inhibitors - used for acid problems in your stomach such as indigestion
- phosphate binders as sevelamer - used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood. These products should be taken at least 2 hours after taking mycophenolate mofetil.
- antacids that contain magnesium and aluminum (mycophenolate mofetil and the antacid should not be taken at the same time).
- antibiotics – used to treat bacterial infections as sulfamethoxazole/trimethoprim, norfloxacin, metronidazole, ciprofloxacin
- isavuconazole – used to treat fungal infections
- telmisartan – used to treat high blood pressure
- acyclovir, valacyclovir, ganciclovir, valganciclovir.
- Oral contraceptives, their effect will decrease by concomitant administration with mycophenolate mofetil (see “contraception” below)

Know the medicines you take. Keep a list of them to show to your doctor or nurse and pharmacist when you get a new medicine. Do not take any new medicine without talking with your doctor.

Vaccines

If you need to have a vaccination (a live vaccine) while taking Mycophenolate mofetil, talk to your doctor or pharmacist first. Your doctor will have to advise you on which vaccines you can have. live attenuated vaccines should be avoided (e.g., intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow).

Contraception in women taking Mycophenolate mofetil

If you are a woman who could become pregnant:

- you must provide a negative pregnancy test before starting treatment and another pregnancy test 8 to 10 days later. Pregnancy tests should be repeated during routine follow-up visits with your doctor. Talk to your doctor about the results of all of your pregnancy tests.
- You must follow the contraception advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.
- You must use acceptable birth control before you start treatment with mycophenolate mofetil, during your entire mycophenolate mofetil treatment and for 6 weeks after stopping mycophenolate mofetil, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely.
- Mycophenolate mofetil 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 mycophenolate mofetil, and you could become pregnant. If you take birth control pills while using mycophenolate mofetil you must also use another form of birth control. Talk to your doctor about other birth control methods that you can use while taking mycophenolate mofetil.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy. **Contact your doctor as soon as possible, if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.**

Contraception in men taking Mycophenolate mofetil

The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, a risk cannot be completely excluded. As a precaution, you or your female partner are recommended to use reliable contraception during treatment and for 90 days after you stop taking Mycophenolate mofetil.

If you are planning to have a child, talk to your doctor about the potential risks and alternative therapies.

Pregnancy and breast-feeding

Pregnancy

Mycophenolate causes a very high frequency of miscarriage (50%) and of severe birth defects (23 - 27 %) in the unborn baby. Birth defects which have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, esophagus (tube that connects the throat with the stomach), kidneys and nervous system (for example spina bifida (where the bones of the spine are not properly developed)). Your baby may be affected by one or more of these.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ if:

- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have sex without using effective methods of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking Mycophenolate mofetil until you see him or her.

Breast-feeding

Do not take Mycophenolate mofetil if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Driving and using machines

Mycophenolate mofetil may influence your ability to drive and use machines (See section 4). If you experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with mycophenolate mofetil, you should be cautious about driving or using heavy machines and talk to your doctor or nurse.

Important information about some of the ingredients of Mycophenolate mofetil

- Mycophenolate mofetil contains aspartame. If you have a rare problem with your metabolism called "phenylketonuria", talk to your doctor before you start taking this medicine.
- Mycophenolate mofetil contains sorbitol (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Mycophenolate mofetil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The amount you take depends on the type of transplant you have had. The usual doses are shown below. Treatment will continue for as long as you need to prevent rejection of your transplant organ. Take mycophenolate mofetil exactly as prescribed. Do not stop taking mycophenolate mofetil or change the dose unless your doctor tells you to.

Mycophenolate powder for oral suspension is usually used as soon as possible following transplantation when you are able to take oral medications..

Kidney transplant

Adults

- The daily dose is 10 ml suspension (2 g of the medicine) taken as 2 separate doses.
- Take 5 ml suspension in the morning and then 5 ml suspension in the evening.

Children

- 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 square meters or “m²”). The recommended dose is 600 mg/m² taken twice a day (up to a maximum of 2 g/10 ml oral suspension daily).

Heart transplant

Adults

- The daily dose is 15 ml suspension (3 g of the medicine) taken as 2 separate doses.
- Take 7.5 ml suspension in the morning and then 7.5 ml suspension in the evening.

Children

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

Liver transplant

Adults

- The daily dose is 15 ml suspension (3 g of the medicine) taken as 2 separate doses.
- Take 7.5 ml suspension in the morning and then 7.5 ml suspension in the evening.

Children

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

Making up the medicine

The medicine comes as a powder. This needs mixing with purified water before using. Your pharmacist will normally make up the medicine for you. If you need to do it yourself, see section 7 “Making up the medicine”

Taking the medicine

Take mycophenolate mofetil for oral suspension on an empty stomach, unless your doctor tells you otherwise.

Mycophenolate mofetil for Oral Suspension should not be mixed with any type of liquids before taking or giving the dose.

Do not inhale the dry powder. Also, do not get it on your skin, inside your mouth or nose. Take care not to let the powder or the made-up medicine get into your eyes.

- If this happens, rinse your eyes with plain water.

Take care not to let the powder or the made-up medicine get onto your skin.

- If this happens, wash the area thoroughly with soap and water.

If you spill any Mycophenolate mofetil for Oral Suspension, wipe it up using paper towels wet with water. Put the child-resistant bottle cap back on the bottle and wipe the outside of the bottle with wet paper towels.

Taking the medicine

- Always use the oral dispenser provided with Mycophenolate mofetil for Oral Suspension to make sure you measure the right amount of medicine. If your Mycophenolate mofetil for Oral Suspension does not come with the oral dispenser, contact your pharmacist.
- Call your pharmacist if your oral dispenser is lost or damaged.
- Your pharmacist will write the expiration date on your Mycophenolate mofetil for Oral Suspension bottle label. **Do not** use Mycophenolate mofetil after the expiration date.
- Ask your doctor or pharmacist if you have any questions or are unsure about how to take or give the right amount of medicine.

To take a dose of Mycophenolate mofetil for Oral Suspension, you will need the bottle of medicine and an oral dispenser provided with the medicine (**See Figure 1**). Your pharmacist will insert the bottle adapter in the Mycophenolate mofetil for Oral Suspension bottle.

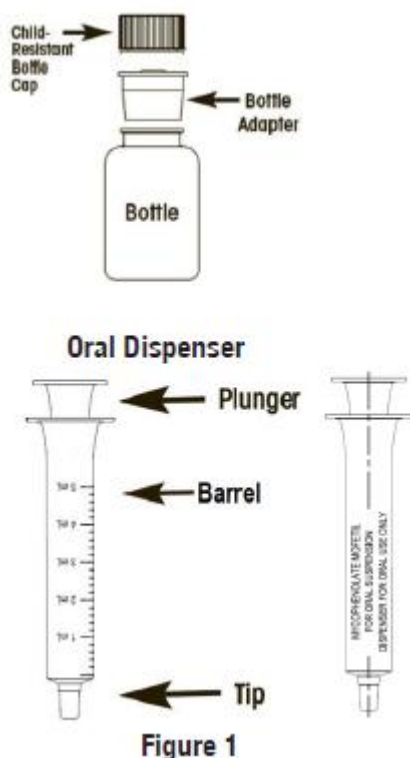


Figure 1

1. With the child-resistant cap on the bottle, shake the closed bottle well for about 5 seconds before each use.
2. Open the bottle by firmly pressing down on the child-resistant bottle cap and turning it to the left (counter-clockwise). **Do not** throw away the child-resistant bottle cap.
3. Take the dispenser and push the plunger completely down toward the tip of the dispenser.
4. Then put the tip of the dispenser firmly into the opening of the bottle adapter.

5. Turn the whole thing upside down with the oral dispenser in place (bottle and dispenser – Figure 2 below).

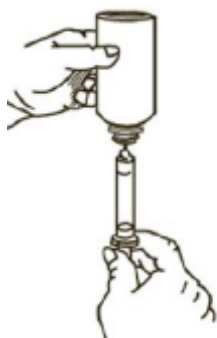


Figure 2

6. Pull the plunger out slowly. Keep pulling it out until the desired amount of medicine is in the dispenser.
7. Turn the whole thing back round the right way.
Holding onto the body of the dispenser, carefully pull the dispenser out of the bottle adapter.
The bottle adapter should stay in the bottle.
Put the end of the dispenser directly into your mouth and swallow the medicine.
Do not mix the medicine with any other liquid when you swallow it. Close the bottle with the child safety bottle cap after each use.
8. Immediately after use – take the dispenser to pieces and rinse it under running tap water. Allow it to dry in the air before using it again.
Do not boil the oral dispenser. **Do not** use solvent-containing wipes for cleaning. **Do not** use cloths or wipes for drying.

Contact your doctor, pharmacist, or nurse if both dispensers are lost or damaged, and they will advise you on how to continue to take your medication.

If you take more Mycophenolate mofetil than you should

If you take more Mycophenolate mofetil 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

If you miss a dose of mycophenolate mofetil, or you are not sure when you took your last dose, take your prescribed dose of mycophenolate mofetil as soon as you remember. If your next dose is less than 2 hours away, skip the missed dose and take your next dose at your normal scheduled time. Do not take 2 doses at the same time. Call your doctor if you are not sure what to do.

If you stop taking Mycophenolate mofetil

Do not stop taking Mycophenolate mofetil unless your doctor tells you to. If you stop your treatment, you may increase the chance of rejection of your transplant organ. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Talk to a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding
- you have a rash, swelling of your face, lips, tongue, or throat, with difficulty breathing – you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema).

Usual problems

Some of the more usual problems are diarrhea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

- the number of your blood cells or signs of infections.

Children may be more likely than adults to have some side effects. These include diarrhea, infections, fewer white cells and fewer red cells in the blood.

Fighting infections

Mycophenolate mofetil reduces your body's defenses. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

Serious infections can happen with mycophenolate mofetil and can lead to hospitalizations and death. These serious infections can include:

Viral infections. Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with mycophenolate mofetil include:

- Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.
- BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
- Hepatitis B and C viruses. Hepatitis viruses can affect how your liver works. Talk to your doctor about how hepatitis viruses may affect you.

A brain infection called Progressive Multifocal Leukoencephalopathy (PML). In some patients, mycophenolate mofetil 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. Call your doctor right away if you have any of the following symptoms:

- weakness on one side of the body
- you are confused or have problems thinking
- you do not care about things you usually care about (apathy)
- you cannot control your muscles

Fungal infections. Yeasts and other types of fungal infections can happen with mycophenolate mofetil and can cause serious tissue and blood infections (See section 4)

Lymph and skin cancer

People who take mycophenolate mofetil have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your doctor 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

General unwanted effects

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle), headache, flu symptoms and swelling.

The most common side effects of mycophenolate mofetil include:

- diarrhea
- blood problems including low white blood cells in particular neutrophils, low red blood cell counts, low platelets
- infections
- blood pressure problems
- fast heartbeat
- swelling of the lower legs, ankles and feet
- changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia)
- stomach problems including diarrhea, constipation, nausea and vomiting, bleeding, loss of appetite
- rash, itching
- nervous system problems such as headache, dizziness and tremor, changes in mood.

Side effects that can happen more often in children than in adults taking mycophenolate mofetil include:

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

These are not all of the possible side effects of mycophenolate mofetil. Tell your doctor about any side effect that bothers you or that does not go away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the National Pharmacovigilance Centre (NPC) – SFDA. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mycophenolate mofetil

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP.
- The shelf-life of the reconstituted suspension is two months. Do not use the suspension past this expiry date.
- Powder for oral suspension: do not store above 30°C.
- Reconstituted suspension: do not store above 30°C. It can be kept under refrigeration at 2°C to 8°C. Do not freeze.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Mycophenolate mofetil contains

The active substance is mycophenolate mofetil. Each bottle contains 35 g mycophenolate mofetil.

The other ingredients are Aspartame, banana flavor (contains Arabic gum, natural flavor, potato maltodextrin, medium chain triglycerides), citric acid anhydrous, colloidal silicon dioxide, Isopropyl alcohol*, lecithin granular, methylparaben, sodium citrate dihydrate, sorbitol, xanthan gum

*evaporated during processing; negligible amount may be present.

What Mycophenolate mofetil looks like and contents of the pack

Each bottle contains 35 g of mycophenolate mofetil.

When reconstitute with 91 ml of purified water, each 5 ml of the reconstituted suspension contain 1 g of mycophenolate mofetil.

A bottle adapter and 2 oral dispensers are also provided.

Making up the medicine

Your pharmacist will normally make up the medicine for you. If you need to do it yourself, follow the steps below:

The following are the steps for reconstitution:

1. Tap the closed bottle several times to loosen the powder.
2. Measure 91 mL of water in a graduated cylinder.
3. Add approximately half the total amount of water for reconstitution to the bottle and shake the closed bottle well for about 1 minute.
4. Add the remainder of water and shake the closed bottle well for about 1 minute.
5. Remove the child-resistant cap and push bottle adapter into neck of bottle.

6. Close bottle with child-resistant cap tightly. This will assure the proper seating of the bottle
7. adapter in the bottle and child-resistant status of the cap.
8. Write the date of expiration of the constituted suspension on the bottle label. (The shelf-life of the constituted suspension is 60 days.)
9. Dispense with the “Instruction for Use” and oral dispensers. Alert patients to read the important handling information described in the instructions for use.
10. Store reconstituted suspension at 20°C to 25°C; excursions permitted to 15°C to 30°C. Storage in a refrigerator at 2°C to 8°C is acceptable. Do not freeze. Discard any unused portion 60 days after constitution.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

VistaPharm, Inc.
Largo, FL 33771, USA
VP2180R2

Manufacturer

For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:

This leaflet was last revised in 01/ 2022

- To report any side effect(s):
 - **Saudi Arabia:**

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| <ul style="list-style-type: none">• The National Pharmacovigilance Centre (NPC):<ul style="list-style-type: none">- SFDA Call Center: 19999- E-Mail: npc.drug@sfda.gov.sa- Website: www.sfda.gov.sa/npc |
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- **Other GCC States:**

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| <ul style="list-style-type: none">- Please contact the relevant competent authority. |
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<h3 style="text-align: center;">This is a Medicament</h3>
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| <ul style="list-style-type: none">- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.- The doctor and the pharmacist are the experts in medicines, their benefits and risks.- Do not by yourself interrupt the period of treatment prescribed for you.- Do not repeat the same prescription without consulting your doctor.- Keep all medicaments out of reach of children. |
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