2INMYRTJ-AE-062025

Mycophenolate mofetil

Myora 500 mg Film-coated Tablets

PATIENT INFORMATION LEAFLET (PIL)

Myora 500 mg Film-coated Tablets

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The product is known by the name above but will be referred to as Myora throughout the rest of this leaflet.

In this leaflet:

1. What Myora is and what it is used for

Myora contains mycophenolate mofetil.

Myora is indicated in combination with corticosteroids and ciclosporin for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.

2. What you need to know before you take Myora

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 Myora
- If you are allergic to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in this medicine (listed in section 6)
- If you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription, as mycophenolate causes birth defects and miscarriage
- If you are pregnant or planning to become pregnant or think you may be pregnant
- If you are not using effective contraception (see Contraception, pregnancy and breast-feeding)
- If you are breast-feeding.

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 Myora.

Warnings and precautions

Talk to your doctor straight away before starting treatment with Myora:
- 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 are planning to become pregnant or if you get pregnant while you or partner are taking Myora
- If you have a hereditary enzyme deficiency such as Lesch-Nyhan and Kelley-Seegmiller syndrome.

If any of the above apply to you (or you are not sure), talk to your doctor straight away before starting treatment with Myora.

The effect of sunlight

Mycophenolate 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 that also covers your head, neck, arms and legs
- Using a sunscreen with a high protection factor.

Children

Children, especially those under 6 years old, may be more likely than adults to have some side effects, including diarrhoea, vomiting, infections, fewer red cells and fewer white cells in the blood, and possibly lymph or skin cancer.

Tablets are only appropriate for children who are capable of swallowing solid medication without the risk of choking. The medicine should therefore only be given in line with the doctor's prescription.

If you are not sure about anything for your child's treatment, talk to your doctor or pharmacist before use.

Other medicines and Myora

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 Myora can affect the way some other medicines work. Also other medicines can affect the way Myora works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Myora:
- 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)
- Antacids or proton pump inhibitors – used for acid problems in your stomach such as indigestion
- Phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood
- Antibiotics – used to treat bacterial infections
- Isavuconazole – used to treat fungal infections
- Telmisartan – used to treat high blood pressure.

Vaccines

If you need to have a vaccination (a live vaccine) while taking Myora, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

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

Myora with food and drink

Taking food and drink has no effect on your treatment with mycophenolate.

Contraception, pregnancy and breast-feeding

Contraception in women taking Myora

If you are a woman who could become pregnant, you must use an effective method of contraception with Myora. This includes:
- Before you start taking Myora
- During your entire treatment with Myora
- For 6 months after you stop taking Myora.

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.

You cannot become pregnant if any of the following conditions applies to you:
- You are post-menopausal, i.e. at least 50 years old and your last period was more than a year ago (if your periods have stopped because you have had treatment for cancer, then there is still a chance you could become pregnant)
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy)
- Your womb (uterus) has been removed by surgery (hysterectomy)
- Your ovaries no longer work (premature ovarian failure, which has been confirmed by a specialist gynaecologist)
- You were born with one of the following rare conditions that make pregnancy impossible: the XY genotype, Turner's syndrome or uterine agenesis
- You are a child or teenager who has not started having periods.

Contraception in men taking Myora

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 are recommended to use reliable contraception during treatment and for 90 days after you stop taking Myora.

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

Pregnancy and breast-feeding

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 Myora until you see him or her.

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, oesophagus (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 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 may request more than one test to ensure you are not pregnant before starting treatment.

Breast-feeding

Do not take Myora 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 has a moderate influence on your ability to drive or use any tools or machines. If you feel drowsy, numb or confused, talk to your doctor or nurse and do not drive or use any tools or machines until you feel better.

Myora contains sodium

Myora contains sodium. Each film-coated tablet of Myora 500 mg Film-coated Tablets contains 6.74 mg sodium. This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Myora

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

The first Myora dose should be administered as soon as possible after renal, cardiac or hepatic transplantation.

The administration of Myora tablets should begin as soon as oral medication of the patient is possible.

Renal transplant

Adults:

The best therapeutic benefit-risk ratio is observed with a daily dose of 2 g (2 film-coated tablets twice daily). A daily dose of 2 g is generally recommended for renal transplant patients. Where a higher level of immunosuppression appears warranted in selected patients, a daily Myora dose of 3 g (3 film-coated tablets twice daily) can be given.

No dose adjustment is required in patients with delayed postoperative renal graft function. However, patients should be carefully monitored. In renal transplant rejection, no changes occur in the pharmacokinetics of mycophenolic acid (MPA) that make it necessary to reduce the dose or discontinue administration.

Children and adolescents (age 3 months to 18 years):

The recommended dose of mycophenolate is 600 mg/m^2 administered orally twice daily (up to a maximum daily dose of 2 g).

When the solid oral dosage forms are used, patients with a body surface area of 1.25 to 1.5 m^2 may be treated with mycophenolate at a dose of 750 mg twice daily (daily dose: 1.5 g). Patients with a body surface area > 1.5 m^2 may be treated with Myora tablets at a dose of 1 g twice daily (daily dose: 2 g).

Cardiac transplant

Adults:

The recommended dose for cardiac transplant patients is 1.5 g twice daily (daily dose 3 g). In cardiac transplant rejection there is no reason for dose correction.

Children and adolescents:

No data are available for pediatric cardiac transplant patients.

Hepatic transplant

Adults:

The recommended dose for hepatic transplant patients is 1.5 g twice daily (daily dose 3 g). No pharmacokinetic data are available in hepatic transplant rejection.

Children and adolescents:

No data are available for pediatric hepatic transplant patients.

Method of administration

It is recommended that Myora be taken on an empty stomach. Patients with a stable renal graft can take Myora with food.

Special dosage instructions

Patients with renal impairment

In cardiac or hepatic transplant patients with severe chronic renal failure, Myora should be used only if the expected benefit outweighs the potential risk. No data are available in these patients.

Renal transplant recipients with severe chronic renal failure (glomerular filtration rate <25 ml/min/1.73 m^2) who were given single oral doses of mycophenolate had higher AUC values for plasma mycophenolic acid and mycophenolic acid glucuronide (MPAG) than patients with minor renal impairment or healthy subjects. Such renal transplant recipients should not be treated with Myora doses higher than 1 g twice daily and must be carefully monitored.

Patients with hepatic impairment

Dose adjustment is not recommended in renal transplant recipients with severe parenchymal liver disease.

No data are available on cardiac transplant recipients with severe parenchymal liver disease.

Myelosuppression

For patients who develop neutropenia (absolute neutrophil count [ANC] <1.3x10^3/µl), Myora must be discontinued or its dose reduced. Appropriate diagnostic tests should also be performed and treatment given, if required.

Elderly patients

In elderly patients the same dose is recommended as in adults. Patients in this age group are at increased risk of side effects.

If you take more Myora than you should

If you take more Myora 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 Myora

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 missed dose.

If you stop taking Myora

Do not stop taking Myora 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 questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, mycophenolate 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 diarrhoea, 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.

Fighting infections

Mycophenolate reduces your body's defences. 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.

Lymph and skin cancer

As can happen in patients taking this type of medicine (immune-suppressants), a very small number of patients on mycophenolate have developed cancer of the lymphoid tissues and skin.

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.

Other unwanted effects may include:

Skin problems such as:
- Acne, cold sores, shingles, skin growth, hair loss, rash, itching.

Urinary problems such as:
- Blood in the urine.

Digestive system and mouth problems such as:
- Swelling of the gums and mouth ulcers,
- Inflammation of the pancreas, colon or stomach,
- Gastrointestinal disorders including bleeding,
- Liver disorders,
- Diarrhoea, constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence.

Nervous system problems such as:
- Feeling dizzy, drowsy or numb,
- Tremor, muscle spasms, convulsions,
- Feeling anxious or depressed, changes in your mood or thoughts.

Heart and blood vessel problems such as:
- Change in blood pressure, accelerated heartbeat, widening of blood vessels.

Lung problems such as:
- Pneumonia, bronchitis,
- Shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lung). Talk to your doctor if you develop a persistent cough or breathlessness,
- Fluid on the lungs or inside the chest
- Sinus problems.

Other problems such as:
- Weight loss, gout, high blood sugar, bleeding, bruising.

Additional side effects in children and adolescents

Children, especially those under 6 years old, may be more likely than adults to have some side effects, including diarrhoea, vomiting, infections, fewer red cells and fewer white cells in the blood, and possibly lymph or skin cancer.

5. How to store Myora

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the package after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Myora contains

The active substance is mycophenolate mofetil.

Each film-coated tablet of Myora 500 mg Film-coated Tablets contains 500 mg mycophenolate mofetil.

The other ingredients are povidone, croscarmellose sodium, microcrystalline cellulose, magnesium stearate and Opadry grey.

What Myora looks like and contents of the pack

Myora 500 mg Film-coated Tablets are lavender coloured, capsule-shaped film-coated tablets embossed with "MH6" in PVC/PVDC-aluminum blisters.

Pack sizes: 50 and/or 150 Film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Batch releaser

The Arab Pharmaceutical Manufacturing PSC
P.O. Box 42
Sult, Jordan
Tel: + (962-5) 3492200
Fax: + (962-5) 3492203

Manufacturer

The Arab Pharmaceutical Manufacturing PSC
Sahab
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This leaflet was last revised in 06/2025; version number JO1.0.

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 (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

- Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance Department
e-mail: jpc@jfda.jo
Website: https://vigiflow-eforms.who-umc.org/jo/jpc
Tel: + (962-6) 5632000
QR Code:

- Saudi Arabia

The National Pharmacovigilance Centre (NPC)
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

- Other GCC States

Please contact the relevant competent authority.

- Sultanate of Oman

Department of Pharmacovigilance & Drug Information
Drug Safety Center
Ministry of Health, Sultanate of Oman
Phone Nos. 0096822357687 / 0096822357690
Fax: 0096822358489
Email: pharma-vigil@moh.gov.om
Website: www.moh.gov.om

Council of Arab Health Ministers, Union of Arab Pharmacists

This is a Medicament
- 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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Size: 345 x 515 mm

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