Package Leaflet: Information for the User

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

1. What Mycophenolate Mofetil Mylan is and what it is used for

Mycophenolate Mofetil Mylan contains the active substance mycophenolate mofetil.

Mycophenolate Mofetil Mylan belongs to a group of medicines called immunosuppressants. These medicines are used to prevent your body rejecting a transplanted kidney, heart or liver. Mycophenolate Mofetil Mylan should be used together with other medicines known as ciclosporin and corticosteroids.

2. What you need to know before you take Mycophenolate Mofetil Mylan

Do not take Mycophenolate Mofetil Mylan:

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

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

Warnings and precautions:
Talk to your doctor or pharmacist before taking Mycophenolate Mofetil Mylan:

- if you experience any evidence of infection such as fever or sore throat
- if you have any unexpected bruising or bleeding
- if you 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 taking Mycophenolate Mofetil Mylan
- if you have a rare enzyme hereditary disorder known as deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) 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 or pharmacist straight away before taking Mycophenolate Mofetil Mylan.

The effect of sunlight

Mycophenolate Mofetil Mylan 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 appropriate protective clothing , which also covers your head, neck, arms and legs
- using a sunscreen with a high protection factor.

Other medicines and Mycophenolate Mofetil Mylan:
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.This includes medicines obtained without a prescription, including herbal medicines. This is because Mycophenolate Mofetil Mylan can affect the way other medicines work. Also other medicines can affect the way Mycophenolate Mofetil Mylan works.

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

- azathioprine or medicines which suppress your immune system
- cholestyramine used to treat high cholesterolrifampicin 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

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

Mycophenolate Mofetil Mylan with food and drink
Taking food and drink has no effect on your treatment with Mycophenolate Mofetil Mylan.

Pregnancy, contraception and breast-feeding

Pregnancy
- If you are pregnant, do not take Mycophenolate Mofetil Mylan. This is because Mycophenolate Mofetil Mylan may cause miscarriage or damage to your unborn baby (affecting development of ears for example).
  - In certain situations, you and your doctor may decide that the benefits of taking Mycophenolate Mofetil Mylan for your health are more important than the possible risks to your unborn baby.
- **If you plan to become pregnant**, talk to your doctor first. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- **If you think you may be pregnant tell your doctor straight away.**
  - However, keep taking Mycophenolate Mofetil Mylan until you see him or her.

If you are able to become pregnant, you must have a pregnancy test before you start Mycophenolate Mofetil Mylan. You can only start Mycophenolate Mofetil Mylan if the test is negative.

You are a woman who is not capable of becoming pregnant if any of the following 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
You must always use an effective method of contraception with Mycophenolate Mofetil Mylan. This includes:
- before you start taking Mycophenolate Mofetil Mylan
- during your entire treatment with Mycophenolate Mofetil Mylan
- for 6 weeks after you stop taking Mycophenolate Mofetil Mylan.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation.

Breast-feeding
Do not take Mycophenolate Mofetil Mylan 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 Mylan is not likely to affect you being able to drive or use any tools or machines.

3. How to take Mycophenolate Mofetil Mylan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The amount you take depends on the type of transplant you have had. The recommended doses are shown below. Treatment will continue for as long as you need to prevent you from rejecting your transplant organ.

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

Use in children 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 square metres or "m^2"). The recommended dose is 600 mg/m^2 taken twice a day.

Use in children below 2 years of age
- There is no information for the use of Mycophenolate Mofetil Mylan in children with a kidney transplant and therefore the use is not recommended.

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

Use in children
There is no information for the use of Mycophenolate Mofetil Mylan in children with a heart transplant.

Liver Transplant
Adults
- The first dose of oral Mycophenolate Mofetil Mylan will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medications.

- The recommended daily dose is 6 tablets (3 g of the active ingredient) taken as 2 separate doses.
- Take 3 tablets in the morning and then 3 tablets in the evening.

Use in children
- There is no information for the use of Mycophenolate Mofetil Mylan in children with a liver transplant

Method of administration
- Swallow your tablets whole with a glass of water.
- Do not break or crush them.

If you take more Mycophenolate Mofetil Mylan than you should

If you take more tablets than you have been told to take, or if someone else accidentally takes your medicine, immediately see a doctor or go to a hospital straight away. Your body's defense mechanism can be reduced increasing the risk of infections. Take the medicine pack with you.

If you forget to take Mycophenolate Mofetil Mylan

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 Mylan

Stopping your treatment with Mycophenolate Mofetil Mylan may increase the chance of rejection of your transplanted organ. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can have 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:

Very common - may affect more than 1 in 10 people:
- decrease in the normal amounts of different blood cells, which can result in frequent infections, unexpected bruising or bleeding, fever or sore throat. Your doctor will do regular blood tests to check for any changes in the number of your blood cells
- serious bacterial infection of the blood (sepsis) with high fever, chills, headache, confusion and rapid breathing.

Common side effects - may affect up to 1 in 10 people
- inflammation of the liver, yellowing of the skin and whites of the eyes

Uncommon - may affect up to 1 in 100 people:
- severe reduction in the number of white blood cells, which makes infections more likely (agranulocytosis). Symptoms include high temperature and ulcers in the mouth and throat.

Not known (frequency cannot be estimated from the available data**)**:
- wheezing or difficulty breathing, difficulty swallowing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin, which may be signs of a serious allergic reaction (such as anaphylaxis, angioeodema)

- vision changes, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what others say, and muscle weakness, symptoms of a severe infection of the brain cells (Progressive Multifocal Leukoencephalopathy)
- inflammation or infections of the heart and its valves and of the membrane that covers the brain and spinal cord
- abnormal scarring and thickening of the lung tissue (pulmonary fibrosis), causing shortness of breath, cough, and a condition in which the lung airways are abnormally dilated (bronchiectasis). Talk to your doctor if you develop a persistent cough or breathlessness
- Other lung problems such as serious infections and inflammation of lungs, condition in which you may have fever, chills, shortness of breath, cough occasionally with blood

Other possible side effects:

Very common - may affect more than 1 in 10 people:
- diarrhoea, vomiting, feeling sick (nausea), stomach pain
- bacterial, fungal and viral infections of the digestive and urinary tract, cold sores and shingles.

Common - may affect up to 1 in 10 people:
- changes in different laboratory parameters, including increase in liver enzymes, renal parameters such as creatinine, potassium, blood sugar, blood lipids, cholesterol, phosphates, magnesium, calcium and uric acid. Your doctor will do regular blood tests to check for any changes in the amount of things like sugar, fat or cholesterol in your blood
- altered blood count (increased or decreased number of cells in the blood)
- kidney problems with increased levels of urea
- disorders of the digestive system such as constipation, indigestion, excessive wind, belching, inflammation of the mouth, oesophagus, stomach, intestine, liver or pancreas and gastrointestinal bleeding
- convulsions, increased tension in the muscles, shaking and muscle weakness, joint pain
- confusion, agitation, depression, anxiety, changes in your mood or thoughts, drowsiness, sleeplessness, dizziness and headache, tingling or numbness, change of the sense of taste, loss of appetite, weight loss
- inflammation of the sinuses, flu symptoms, sore throat, runny and itchy nose
- skin cancer or non cancerous growths of the skin and fungal infections of the skin and vagina, acne, skin growth, hair loss and rashes
- changes in blood pressure, faster heart beat, widening of blood vessels
- fluid on lungs/chest cavity, gout
- fluid retention in the body, fever, discomfort, lethargy, weakness and swelling of the gums
- inflammation of the liver, yellowing of the skin and whites of the eyes

Uncommon - may affect up to 1 in 100 people:
- proliferation of the lymphatic tissue, including malignant tumours.

Side effects in children
Children may be more likely than adults to have side effects such as diarrhoea, infections, serious bacterial infection of the blood (sepsis), fewer white cells and fewer red cells in the blood.

Elderly patients
Elderly patients receiving Mycophenolate Mofetil Mylan as part of a combination immunosuppressive therapy may be at increased risk of certain infections, fluid build up in the lungs and bleeding in the intestine.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:

medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mycophenolate Mofetil Mylan

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, blister and bottle after "EXP". The expiry date refers to the last day of that month.

Blisters: Store below 25°C. Store in the original container in order to protect from moisture.
Bottles: Store below 25°C. Store in the original container in order to protect from moisture. Use within 90 days of opening. Once open keep bottle tightly closed.

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 to protect the environment.

6. Contents of the pack and other information

What Mycophenolate Mofetil Mylan contains

- The active substance is mycophenolate mofetil. Each film-coated tablet contains 500 mg mycophenolate mofetil.
  The other ingredients are: Tablet core: cellulose, microcrystalline; maize starch, pregelatinised; povidone (K-30); silica, colloidal anhydrous; magnesium stearate; sodium lauril sulfate; croscarmellose sodium.Tablet coating: poly (vinyl alcohol), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide red (E172), iron oxide yellow (E172).

What Mycophenolate Mofetil Mylan looks like and contents of the pack

Your medicine is in the form of a film-coated tablet.

Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets are light pink coloured, oval-shaped tablet engraved with "MYLAN" on one side of the tablet and "472" on the other side.

Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets are available in blisters packs and bottles of 20, 50, 60, 120, 150, 180, 300, 450, 500 film-coated tablets and perforated blister packs of 20x1, 50x1, 60x1, 120x1, 150x1, 180x1, 300x1, 450x1, 500x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom
Delpharm Lille S.A.S, Z.I. de Roubaix Est – Rue de Toufflers, 59 390 LYS-LEZ-LANNOY, France

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Mycophenolatmofetil Mylan 500 mg Filmtabletten
Belgium	Mycophenolate Mofetil Mylan 500 mg filmomhulde tabletten
Bulgaria	Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets
Czech Republic	Mycophenolate Mofetil Mylan 500 mg potahované tablety
Denmark	Mycophenolate mofetil Mylan
Finland	Mycophenolate mofetil Mylan 500 mg kalvopäällysteiset tabletit
France	Mycophenolate Mofetil Mylan 500 mg, comprimé pelliculé
Greece	Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets
Ireland	Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets
Italy	Micofenolato Mofetile Mylan 500 mg Compresse rivestite con film
Poland	Mycophenolate mofetil Mylan, 500mg, tabletki powlekane
Portugal	Micofenolato de mofetil Mylan
Romania	Micofenolat mofetil Mylan 500 mg comprimate filmate
Slovakia	Mycophenolate Mofetil Mylan 500 mg Filmom obalené tablety
Slovenia	Mofetilmikofenolat Mylan 500 mg filmsko obložene tablete
Spain	Micofenolato de mofetilo Mylan 500 mg comprimidos con película
The Netherlands	Mycofenolaat Mofetil Mylan 500 mg, filmomhulde tabletten
United Kingdom	Mycophenolate Mofetil Mylan 500 mg Film-coated Tablets

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