

PACKAGE LEAFLET: INFORMATION FOR THE USER**Mycophenolate Mofetil 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.

What is in this leaflet:

- 1 What Mycophenolate Mofetil Tablets is and what it is used for
- 2 What you need to know before you take Mycophenolate Mofetil Tablets
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1 What Mycophenolate Mofetil Tablets is and what it is used for

Immunosuppressants.

Mycophenolate Mofetil Tablets are used to prevent your body rejecting a transplanted kidney, heart or liver. Mycophenolate Mofetil Tablets is used together with other medicines known as ciclosporin and corticosteroids.

2 What you need to know before you take Mycophenolate Mofetil Tablets**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 Tablets

- * 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 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 Pregnancy, contraception and breast-feeding)
- * If you are breastfeeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Mycophenolate Mofetil Tablets.

You should inform your doctor immediately

- * If you experience any evidence of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding.
 - * If you have or ever have had any problems with your digestive system, e.g. stomach ulcers.
 - * If you are planning to become pregnant, or if you fall pregnant while taking Mycophenolate Mofetil
 - * If you are having rare hereditary 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 straight away before taking Mycophenolate Mofetil.

Children and adolescents**Paediatric population aged 2 to 18 years:**

Mycophenolate Mofetil Tablets are used in children and adolescents (aged 2 to 18) to prevent a body rejecting a transplanted kidney. Mycophenolate Mofetil Tablets should not be used in children and adolescents (aged 2 to 18) for heart or liver transplantation. Mycophenolate Mofetil Tablets should not be used in children under 2 years old.

The effect of sunlight

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

Other medicines and Mycophenolate Mofetil Tablets:

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines.

This includes medicines obtained without a prescription, including 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 which 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
- * aciclovir, valaciclovir or ganciclovir

Vaccines

If you need to have a vaccine (a live vaccine) while taking Mycophenolate Mofetil, 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 Mycophenolate Mofetil and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with Mycophenolate Mofetil and at least 90 days after stopping treatment.

Mycophenolate Mofetil Tablets with food and drink:

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

Pregnancy, contraception and breast-feeding**Contraception in women taking Mycophenolate Mofetil Tablets**

If you are a woman who could become pregnant you must always use two effective methods of contraception with Mycophenolate Mofetil Tablets. This includes:

- * Before you start taking Mycophenolate Mofetil Tablets
 - * During your entire treatment with Mycophenolate Mofetil Tablets
 - * For 6 weeks after you stop taking Mycophenolate Mofetil Tablets
- 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 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 in men taking Mycophenolate Mofetil Tablets

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

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 an effective method of contraception.
- If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking Mycophenolate Mofetil Tablets 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 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 Tablets has not been shown to impair your ability to drive or operate machinery.

Mycophenolate Mofetil[®] 500 mg Film-coated Tablets

mycophenolate mofetil

3 How to take Mycophenolate Mofetil Tablets

Always take Mycophenolate Mofetil exactly as your doctor has told you. You should 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 you from rejecting your transplant organ.

Kidney transplant

Adults

- * The first dose is given within 3 days of the transplant operation.
- * The 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.

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 “m²”). The recommended dose is 600 mg/ m² taken twice a day.

Heart transplant

Adults

- * The first dose is given within 5 days of the transplant operation.
- * The 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.

Children

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

Liver transplant

Adults

- * The first dose of oral Mycophenolate Mofetil will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medicines.
- * The 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.

Children

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

Method and route of administration:

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

If you take more Mycophenolate Mofetil Tablets than you should

If you take more Mycophenolate Mofetil Tablets than you have been told to take, or if someone else accidentally takes Mycophenolate Mofetil Tablets, immediately see a doctor or go to a hospital straight away. 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 missed dose

If you stop taking Mycophenolate Mofetil Tablets

Stopping your treatment with Mycophenolate Mofetil Tablets 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 further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine 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).

Other possible side effects:

Very common (may affect more than one in 10 people)

Digestive system and mouth problems such as:

- * feeling sick (nausea)
- * vomiting

Blood and lymphatic system disorders

- * fewer white cells or red cells in your blood

Infections and infestations

- * Stomach and gut infections
- * Urinary system infections
- * Mouth infections

Common (may affect up to 1 in 10 people)

Infections and infestations

- * Lung infections
- * Skin infections

Lymph and skin cancer

- * cancer of the lymphoid tissues and skin.

General disorders

- * fever, feeling very tired, difficulty sleeping
- * pains (such as stomach, chest, joint or muscle, pain on passing urine)
- * headache, flu symptoms and swelling.

Skin problems such as:

- * acne, cold sores, shingles, skin growth, hair loss, rash, itching.

Urinary problems such as:

- * kidney problems or the urgent need to pass water (urine).

Digestive system and mouth problems such as:

- * swelling of the gums and mouth ulcers
- * inflammation of the pancreas, colon or stomach
- * gut problems including bleeding, liver problems
- * constipation, indigestion, loss of appetite, flatulence, diarrhoea.

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, unusual 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

Not known (frequency cannot be estimated from the available data)

Infections and infestations

- * Brain infections

Your doctor will do regular blood tests to check for any changes in:

- * the number of your blood cells
 - * the amount in your blood of things like sugar, fat or cholesterol.
- Children may be more likely than adults to have some side effects. These include diarrhoea, infections, fewer white cells and fewer red cells in the blood.

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 HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Mycophenolate Mofetil Tablets

- * Do not store above 25°C. Keep the blister in outer carton in order to protect from light.
- * 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 blister and carton after EXP. The expiry date refers to the last day of that month. Always return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.
- * 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 Mycophenolate Mofetil Tablets contain:

The active substance is 500mg as mycophenolate mofetil.

The other ingredients are :

Tablet core : microcrystalline cellulose, povidone, hydroxypropyl cellulose, croscarmellose sodium, talc, magnesium stearate.

Tablet coating: hypromellose 6cps, titanium dioxide (E171), macrogol 400, red iron oxide (E172), indigo carmine (E132), black iron oxide (E172).

What Mycophenolate Mofetil 500 mg Tablets look like and contents of the pack

Mycophenolate Mofetil Tablets 500 mg are purple coloured, capsule shaped, biconvex, film-coated tablet debossed 'AHI' on one side and '500' on the other side.

Mycophenolate Mofetil Tablets are packed in a white opaque PVC/PVdC- aluminium blisters packed in a final carton along with package insert, and come in packs of 50 tablets.

Parallel distributed by:

Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by:

Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland.

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