

Package leaflet: Information for the user
Mycophenolate Mofetil 500mg 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, please 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 Tablets are and what they are used for
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1. What Mycophenolate Tablets are and what they are used for

The name of your medicine is Mycophenolate Mofetil 500mg Film-Coated Tablets (referred to Mycophenolate Tablets in this leaflet).

Mycophenolate Tablets contain the active substance mycophenolate mofetil. Mycophenolate Mofetil belongs to a group of medicines called immunosuppressants, which are used to inhibit the activity of the immune system (your body's defence mechanism against infection).

Mycophenolate Tablets should be used in combination with other medicines called ciclosporin and corticosteroids, to prevent your body rejecting a new kidney, liver or heart following a transplant.

2. What you need to know before you take Mycophenolate 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 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 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 Pregnancy, contraception 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 Mycophenolate Tablets.

Warnings and precautions**Talk to your doctor before taking Mycophenolate Tablets:**

- 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 taking Mycophenolate Tablets
- If you suffer from either Lesch-Nyhan or 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 Tablets.

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

Other medicines and Mycophenolate Tablets

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 Tablets can affect the way some other medicines work. Also other medicines can affect the way Mycophenolate Tablets work.

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

- azathioprine or other medicines which suppress your immune system – given after a transplant operation.
- colestyramine - 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 such as sevelamer - 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 - used to treat herpes and shingles
- probenecid - used to treat gout

Vaccines

If you need to have a vaccine (a live vaccine) while-taking Mycophenolate Tablets, talk to your doctor first. Your doctor will have to advise you on what vaccines you can have.

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

Mycophenolate tablets with food and drink

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

Pregnancy, contraception and breast-feeding

Contraception in women taking Mycophenolate Tablets

If you are a woman who could become pregnant you must use an effective method of contraception with Mycophenolate Tablets. This includes:

- Before you start taking Mycophenolate Tablets
- During your entire treatment with Mycophenolate Tablets
- For 6 weeks after you stop taking Mycophenolate 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 (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 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 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 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 Tablets 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 Tablets are not likely to affect your ability to drive or use machines.

3. How to take Mycophenolate Tablets

Always take Mycophenolate Tablets 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 you from rejecting your transplant organ.

Kidney Transplant

Adults

- The first dose will be given to you 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 after your 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 Tablets in children with a heart transplant.

Liver Transplant

Adults

- The first dose of Mycophenolate Tablets will be given to you at least 4 days after the transplant operation, and when you can are able to swallow oral medicines.
- The usual 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 Tablets in children with a liver transplant.

Taking the medicine

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

If you take more Mycophenolate Tablets than you should

If you take more Mycophenolate Tablets than you should, talk to doctor or go to a hospital straight away. Also do this if someone else accidentally takes your medicine. Take the medicine pack with you to show the doctor.

If you forget to take Mycophenolate 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 Tablets

Do not stop taking Mycophenolate Tablets unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your the 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 Tablets 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
- 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.

Fighting infections

Mycophenolate Tablets reduce 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 mycophenolate patients 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, pain on passing urine), 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:

- 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, 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, 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, bleeding, bruising.

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 reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Store in the original container in order to protect from light.
- Do not use Mycophenolate Tablets after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Mycophenolate Tablets contains

The active ingredient is: mycophenolate mofetil. Each Mycophenolate Tablet contains 500mg of mycophenolate mofetil.

The other ingredients are:

- Tablet core: microcrystalline cellulose (E460(i)), croscarmellose sodium, povidone, hydroxypropylcellulose (E463), magnesium stearate.
- Tablet coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, purified talc (E553b), indigo carmine aluminium lake (E132), red iron oxide (E172).

What Mycophenolate Tablets look like and contents of the pack

- Mycophenolate tablets are purple coloured film coated tablets engraved with 'W417' on one side and plain on the other.
- Mycophenolate Tablets are available in blister packs packaged in a cardboard carton, containing 50 tablets.

Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK.

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Mycophenolate Mofetil 500 mg Film-Coated Tablets	29831/0427

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call +44 1978 661 261.

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

Republic of Ireland - Mycophenolate Mofetil 500 mg Film-Coated Tablets

United Kingdom - Mycophenolate Mofetil 500 mg Film-Coated Tablets

This leaflet was last revised in 05/2018.