

PACKAGE LEAFLET

Package leaflet: Information for the patient

Mycophenolate Mofetil 500 mg film-coated tablets

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 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 the active substance mycophenolate mofetil, which belongs to a group of medicines called immunosuppressants. These medicines are used to prevent the body rejecting a transplanted organ in adults and Children: A kidney, heart or liver. Mycophenolate Mofetil should be used together with other medicines known as ciclosporin and corticosteroids.

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

WARNING

Mycophenolate mofetil 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 mofetil 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 mofetil. 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 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 mofetil 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.

Warnings and precautions:

Talk to your doctor or pharmacist before taking 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 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
- 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.

During treatment with Mycophenolate Mofetil, talk to your doctor or pharmacist:

- if you experience any evidence of infection such as fever or sore throat
- if you have any unexpected bruising or bleeding

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 appropriate protective clothing, which 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 Mycophenolate Mofetil:

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 can affect the way 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, sirolimus, tacrolimus 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 – for example, magnesium antacids, lansoprazole or pantoprazole
- phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood – for example, sevelamer.
- 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 Mycophenolate Mofetil, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

Additional precautions

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 for at least 90 days after stopping treatment.

Pregnancy, contraception and breast-feeding

Contraception in women taking Mycophenolate Mofetil

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

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

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

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.

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 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 is not likely to affect you being able to drive or use any tools or machines, however this medicine can cause you to feel dizzy, sleepy or affect your muscles. If these happen talk to your doctor or pharmacist before driving or using machines.

Mycophenolate Mofetil Mylan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

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 rejection of 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

- 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, talk to your doctor or pharmacist before use.
- The dose given will vary depending on the size of the child.
- Your child's 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 initial dose is 600 mg/m² taken twice a day. The recommended maintenance dose remains at 600 mg/m² twice a day (maximum total daily dose of 2 g). The dose should be individualised based on the doctor's clinical assessment.

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

- 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, talk to your doctor or pharmacist before use.
- The dose given will vary depending on the size of the child.
- Your child's 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 starting dose is 600 mg/m² taken twice a day. The dose should be individualised based on the doctor's clinical assessment. If well tolerated, the dose can be increased to 900 mg/m² twice daily if required (maximum total daily dose of 3 g).

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 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

- 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, talk to your doctor or pharmacist before use.
- The dose given will vary depending on the size of the child.
- Your child's 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 initial dose is 600 mg/m² taken twice a day. The dose should be individualised based on the doctor's clinical assessment. If well tolerated, the dose can be increased to 900 mg/m² twice daily if required (maximum total daily dose of 3 g).

Method of administration

- Swallow your tablets whole with a glass of water.
- Do not break or crush them.
- You can take this medicine with or without food.

If you take more Mycophenolate Mofetil 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 defence mechanism can be reduced increasing the risk of infections. Take the medicine pack with you.

If you forget to take Mycophenolate Mofetil

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

Stopping your treatment with Mycophenolate Mofetil 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 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:

Very common - may affect more than 1 in 10 people:

- decrease in the normal amounts of white blood cells, which can result in frequent infections, causing fever, sore throat and mouth ulcers. 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
- overgrowth of certain fungi in the gut, which can cause you to feel tired or generally unwell, with difficulty thinking or concentrating
- infection with a virus known as 'CMV' (cytomegalovirus), which can cause serious problems with the lungs, liver or bowels. For signs of such problems, read this section carefully

Common - may affect up to 1 in 10 people

- decrease in the normal amounts of other blood cells, which can result in unexpected bruising or bleeding (decreased platelets) or pale skin and tiredness (decreased red blood cells). These may be due to a reduction in all types of blood cells (pancytopenia) or a reduction in the ability of the bone marrow to produce them
- inflammation of the liver, yellowing of the skin and whites of the eyes
- serious infection of the lungs, possibly with a build-up of fluid (pneumonia), causing you to feel generally unwell with fever, chills and cough with mucous, which could be foamed or contain blood
- muscle weakness, which may affect movement, strength, physical exercise, speech or the face
- skin cancer
- convulsions (fits)
- infection in the tissue of the abdomen, causing pain and tenderness
- blockage in the bowel causing persistent constipation, absence of wind, with pain and discomfort
- ulcer or bleeding in the stomach or gut, causing severe pain often following meals, bloating, feeling or being sick, with blood in the vomit or in the stools

Uncommon - may affect up to 1 in 100 people:

- cancer of the lymph glands, or non-cancerous growth of lymph tissue

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, angioedema)
- 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 (endocarditis) and of the membrane that covers the brain and spinal cord (meningitis). These may cause fever, chills, tiredness, sore muscles or joints, shortness of breath, cough, sensitivity of the eyes to light and in serious cases a spotty rash on the skin
- 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 serious infections, which may cause breathing difficulties or cough (tuberculosis), weakness or tiredness, fever, chills, night sweats, loss of appetite and weight loss infection of the colon, causing fever, loss of appetite, weight loss, dehydration, abdominal pain and bloating, feeling or being sick, diarrhoea (possibly with blood) or worsening of existing inflammatory bowel disorder (IBS)
- inflammation of the pancreas, which causes severe stomach pain that spreads to the back

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 the results of some blood tests, including increase in liver enzymes, tests for kidney function such as creatinine, levels of potassium, blood sugar, blood fats, cholesterol, phosphates, magnesium, calcium, uric acid and other acids. Your doctor will do regular tests to check for any changes in the amount of these substances 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 or infection of the mouth, oesophagus, stomach or intestine
- increased tension in the muscles, shaking and 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 and infections of the sinuses, flu symptoms, sore throat, runny and itchy nose
- 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 heartbeat, widening of blood vessels
- fluid on lungs/chest cavity, gout
- fluid retention in the body, fever, discomfort, lethargy, weakness and swelling of the gums.

Additional side effects in children and adolescents

Children, especially those under 6 years old, 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, and possibly lymph or skin cancer.

Elderly patients

Elderly patients receiving Mycophenolate Mofetil 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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, 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 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 laurilsulfate; croscarmellose sodium. Tablet coating: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide red (E172), iron oxide yellow (E172).

What Mycophenolate Mofetil looks like and contents of the pack

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL

Manufacturer

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Other sources of information

Detailed information on this medicine is available on the web site of Medicines and Healthcare Products Regulatory Agency.