Package leaflet: Information for the patient

Mycolat 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 Mycolat is and what it is used for

Mycolat contains mycophenolate mofetil. This belongs to a group of medicines called "**immunosuppressants".**
Mycolat is used to prevent your body rejecting a transplanted organ:
- A kidney, heart or liver.

Mycolat should be used together with other medicines:
- Ciclosporin and corticosteroids.

2. What you need to know before you take Mycolat

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 Mycolat:

- If you are allergic (hypersensitive) 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 Mycolat.

Warnings and precautions

Talk to your doctor straight away before taking Mycolat:

- 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 your partner are taking Mycolat.

If any of the above apply to you (or you are not sure), talk to your doctor straight away before taking Mycolat.

The effect of sunlight

Mycolat 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.

Other medicines and Mycolat

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 Mycolat can affect the way some other medicines work. Also other medicines can affect the way Mycolat works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Mycolat:

- 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
- aciclovir, valaciclovir or ganciclovir - used to treat viral infections.

Vaccines

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

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

Pregnancy, contraception and breast-feeding

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

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 Mycolat
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 Mycolat.
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 an effective method of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking Mycolat 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 that 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 Mycolat 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 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.

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

3. How to take Mycolat

Always take this medicine 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 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 "m^2"). The recommended dose is 600 mg/m^2 taken twice a day.

Use in special populations

Elderly
The recommended dose of 1 g administered twice a day for renal transplant patients and 1.5 g twice a day for cardiac or hepatic transplant patients is appropriate for the elderly.

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 Mycolat 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 Mycolat than you should
If you take more of this medicine 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 Mycolat
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 Mycolat
Do not stop taking this medicine unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your transplant 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, 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, angioeodema).

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.

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.

Very common (may affect more than 1 in 10 people)
- serious infection which may affect the whole body
- fungal infection of the digestive tract
- infection of the urinary tract
- cold sores, shingles
- decrease in the number of white blood cells, platelets or red blood cells, which can result in increased risk of infections, bruising, bleeding, breathlessness and weakness
- vomiting, stomach pain, diarrhoea, feeling sick.

Common (may affect up to 1 in 10 people)
- infection of the lung, flu, infection of the respiratory tract
- infection of the digestive tract
- inflammation of the digestive tract
- infection
- fungal infections (e.g. of the respiratory tract, skin and vagina)
- chest cold, sore throat, inflammation of the sinuses, stuffy and runny nose, sneezing
- skin cancer, non-cancerous growth of the skin
- decrease in the number of all blood cells, increase in the number of white blood cells
- too much acid in the body
- high level of potassium in the blood, low level of potassium, magnesium, calcium and/or phosphate in the blood
- high level of sugar in the blood
- high level of cholesterol and/or lipids in the blood
- high level of uric acid in the blood, gout
- loss of appetite
- feeling restless, abnormalities of thought, perception and levels of awareness, depression, feeling anxious, abnormal thinking, difficulty in sleeping
- fit, increased tension of the muscles, shaking, sleepiness, feeling dizzy, headache, tingling, pricking or numbness
- muscle weakness of the limbs, drooping or falling of the upper eyelid (myasthenic syndrome
- distortion of the sense of taste
- faster heartbeat
- low/high blood pressure, widening of blood vessels

- accumulation of fluid in the lung, shortness of breath, cough
- inflammation of the tissue that lines the inner wall of the abdomen and covers most of the abdominal organs
- bowel blockage
- inflammation of the colon which causes abdominal pain or diarrhoea (sometimes caused by cytomegalovirus), ulcer of the stomach and/or duodenum, inflammation of the stomach, oesophagus and/or mouth and lips
- constipation, indigestion, wind (flatulence), belching
- inflammation of the liver, yellowing of the skin and whites of the eyes
- growth of the skin, rash, acne, hair loss
- joint pain
- blood in the urine
- fluid retention in the body
- fever, feeling of coldness, pain, feeling unwell, feeling weak and feeble
- changes in different laboratory parameters
- weight loss
- overgrowth of the gum tissue
- inflammation of the pancreas, which causes severe pain in the abdomen and back.

Uncommon *(may affect up to 1 in 100 people)*
- proliferation of the lymphatic tissue, including malignant tumours
- severe reduction in the number of certain white blood cells (possible symptoms are fever, sore throat, frequent infections) (agranulocytosis).

Not known *(frequency cannot be estimated from the available data)*
- alterations of the inner wall of the small intestine (intestinal villous atrophy)
- serious inflammation of the membrane that covers the brain and spinal cord
- serious inflammation of the heart and its valves
- bacterial infections usually resulting in a serious lung disorder (tuberculosis, atypical mycobacterial infection)
- serious disease of the kidney (BK virus associated nephropathy)
- serious disease of the central nervous system (JC virus associated progressive multifocal leucoencephalopathy)
- decrease in the number of certain white blood cells (neutropenia)
- serious diseases of the bone marrow
- insufficient production of red blood cells
- change of the shape of certain white blood cells
- 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)
- decrease in the amount of antibodies 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 via the national reporting system: HPRA 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 Mycolat

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 after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Mycolat contains
- The active substance is mycophenolate mofetil.
  Each film-coated tablet contains 500 mg of mycophenolate mofetil.
- The other ingredients are:
  Core content:
  Cellulose microcrystalline, Povidone, Talc, Magnesium stearate, Croscarmellose sodium.
  Coating content:
  Hypromellose, Hydroxypropylcellulose, Titanium dioxide (E171), Macrogol (400); Iron oxide black (E172), Iron oxide red (E172).

What Mycolat looks like and contents of the pack
Mycolat film-coated tablets are lavender coloured, film-coated biconvex tablets, plain on both the sides.

PVC/PE/PVDC/Alu blister
Pack sizes: 50, 150, 250 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Ireland Mycolat 500 mg Film-coated tablets

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