Package leaflet: Information for the patient

Mykofenolatmofetil Actavis 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 Mykofenolatmofetil Actavis is and what it is used for

Mykofenolatmofetil Actavis contains mycophenolate mofetil. This belongs to a group of medicines called “immunosuppressants”.

Mykofenolatmofetil Actavis is used to prevent the body rejecting a transplanted kidney, heart or liver in adults and children.

Mykofenolatmofetil Actavis should be used together with other medicines:
- ciclosporin and corticosteroids.

2. What you need to know before you take Mykofenolatmofetil Actavis

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 “Contraception, pregnancy and breast-feeding”.

Do not take Mykofenolatmofetil Actavis
- 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 “Contraception, pregnancy 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 Mykofenolatmofetil Actavis.

Warnings and precautions
Talk to your doctor before taking Mykofenolatmofetil Actavis:
- 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 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 Mykofenolatmofetil Actavis.
- if you have a hereditary enzyme deficiency 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 Mykofenolatmofetil Actavis.

The effect of sunlight
Mykofenolatmofetil Actavis 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.

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 Mykofenolatmofetil Actavis
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Mykofenolatmofetil Actavis can affect the way some other medicines work. Also other medicines can affect the way Mykofenolatmofetil Actavis works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Mykofenolatmofetil Actavis:
- azathioprine or other medicines which suppress your immune system – given after a transplant operation
- aciclovir – used for treatment and prevention (in immunosuppressed individuals) of viral infections, such as cold sores, genital herpes, shingles and chickenpox
- 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
- medicines that interfere with liver circulation
- ganciclovir (used for treatment and prevention of CMV (cytomegalovirus) infections), especially if you also have kidney problems
- norfloxicin and metronidazole in combination
- 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 Mykofenolatmofetil Actavis, 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 Mykofenolatmofetil Actavis and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with Mykofenolatmofetil Actavis and for at least 90 days after stopping treatment.

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

Contraception, pregnancy and breast-feeding

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

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 cannot become pregnant if any of the following conditions 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 Mykofenolatmofetil Actavis
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 Mykofenolatmofetil Actavis.

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 effective methods of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking Mykofenolatmofetil Actavis 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 Mykofenolatmofetil Actavis if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Driving and using machines
Mykofenolatmofetil Actavis 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.

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

3. How to take Mykofenolatmofetil Actavis

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 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 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
- 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 "m^2"). The recommended initial dose is 600 mg/m^2 taken twice a day. The recommended maintenance dose remains at 600 mg/m^2 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 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
- 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 "m^2"). The recommended initial dose is 600 mg/m^2 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/m^2 twice daily if required (maximum total daily dose of 3 g).

Liver transplant

Adults
- The first dose of oral Mykofenolatmofetil Actavis 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
- 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 "m^2"). The recommended initial dose is 600 mg/m^2 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/m^2 twice daily if required (maximum total daily dose of 3 g).

Taking the medicine

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

If you take more Mykofenolatmofetil Actavis than you should
If you take more Mykofenolatmofetil Actavis 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 Mykofenolatmofetil Actavis
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 Mykofenolatmofetil Actavis
Do not stop taking Mykofenolatmofetil Actavis unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your 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, 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
- rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, lightheadedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening and facial/throat swelling (symptoms of severe allergic reaction)

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

Elderly patients
Elderly patients (≥65 years) may generally be at an increased risk of side effects. Elderly patients receiving Mykofenolatmofetil Actavis in combination with other immunosuppressive medicines, may also be at a greater risk for certain infections, as well as gut bleeding and fluid on the lungs compared to younger patients.

Fighting infections
Mykofenolatmofetil Actavis reduces 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 (immunosuppressants), a very small number of patients on Mykofenolatmofetil Actavis 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), 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:
- blood in the urine.

Digestive system and mouth problems such as:
- swelling of the gums, taste disturbance and mouth ulcers
- inflammation of the food pipe, pancreas, colon or stomach
- gastrointestinal disorders including bleeding and ulcers, liver problems
- diarrhea, constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence and burping/belching.

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, accelerated heart beat, 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.

Additional side effects in children and adolescents
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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mykofenolatmofetil Actavis

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

Do not store above 25°C.
Keep the blister in the outer carton in order to protect from light.

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 Mykofenolatmofetil Actavis contains

- The active substance is mycophenolate mofetil.
  Each film-coated tablet contains 500 mg mycophenolate mofetil.
- The other ingredients are:
  Tablet core: cellulose microcrystalline (E460), povidone, hydroxypropyl cellulose, croscarmellose sodium, talc, magnesium stearate.
  Tablet coating: hypromellose (E464), titanium dioxide (E171), macrogol, iron oxide red (E172), indigo carmine aluminium lake (E132), iron oxide black (E172), talc.

What Mykofenolatmofetil Actavis looks like and contents of the pack

Purple coloured capsule shaped, biconvex film coated tablet, engraved ‘AHI’ on one side and ‘500’ on the other, 18.0 mm in length, 9.0 mm in width and 7.00 mm in thickness.

White opaque PVC/PVdC-Aluminium blister pack
Pack sizes: 50, 100 and 150 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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