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Package leaflet: Information for the user

Mycophenolate Mofetil 250 mg Capsules

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 Capsules is and what it is used for
2. What you need to know before you take Mycophenolate Mofetil Capsules
3. How to take Mycophenolate Mofetil Capsules
4. Possible side effects
5. How to store Mycophenolate Mofetil Capsules
6. Contents of the pack and other information

1. What Mycophenolate Mofetil Capsules is and what it is used for

Mycophenolate Mofetil 250 mg Capsules contains mycophenolate mofetil. This belongs to a group of medicines called “immunosuppressants”.

Mycophenolate Mofetil capsules are used to prevent the body rejecting a transplanted organ in adults and children: kidney, heart or liver.
Mycophenolate Mofetil capsules should be used together with other medicines known as ciclosporin and corticosteroids.

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

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 Capsules:
- 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 Mycophenolate mofetil.

Warnings and precautions
Talk to your doctor straight away before starting treatment with 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 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 Mycophenolate Mofetil.
- 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 starting treatment with Mycophenolate Mofetil.

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 that 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.

Capsules 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 Capsules:
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription such as 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 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

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.
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.

Mycophenolate Mofetil Capsules with food and drink
Taking food and drink has no effect on your treatment with mycophenolate mofetil.

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 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 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 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 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 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 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 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.

Information on sodium content
This product contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take Mycophenolate Mofetil Capsules

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 rejection of your transplant organ.

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Kidney transplant
Adults:
- The first dose is given within 3 days of the transplant operation.
- The daily dose is 8 capsules (2 g of the medicine) taken as 2 separate doses.
- Take 4 capsules in the morning and then 4 capsules in the evening.

Children:
- Capsules 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 12 capsules (3 g of the medicine) taken as 2 separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

Children:
- Capsules 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 2 g).

Liver transplant
Adults:
- The first dose of oral Mycophenolate Mofetil Capsules 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 12 capsules (3 g of the medicine) taken as 2 separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

Children:
- Capsules 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).

Method and Route of Administration
- Swallow your capsules whole with a glass of water.
- Do not break or crush them
- Do not take any capsules that have broken open or split.
- Take care not to let any powder from inside a broken capsule get into your eyes or mouth. If this happens, rinse with plenty of plain water.
- Take care not to let any powder from inside a broken capsule get onto your skin. If this happens, wash the area thoroughly with soap and water.

If you take more Mycophenolate Mofetil Capsules than you should
If you take more mycophenolate mofetil capsules than you should, talk to your 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 Mycophenolate Mofetil Capsules
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 Capsules
Do not stop taking mycophenolate mofetil 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, 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
- 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

Fighting infections
Mycophenolate Mofetil 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 (immune-suppressants), a very small number of patients on Mycophenolate Mofetil 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 and mouth ulcers,
- inflammation of the pancreas, colon or stomach,
- gastrointestinal disorders including bleeding,
- liver disorder,
- diarrhoea, 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, accelerated 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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For UK - You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Mycophenolate Mofetil Capsules

- 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 label or carton after EXP. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not use this medicine if you notice any visible signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mycophenolate Mofetil Capsules contains:
The active substance is Mycophenolate Mofetil. Each capsule contains 250 mg of Mycophenolate Mofetil.

The other ingredients are: cellulose microcrystalline, hydroxy propyl cellulose, povidone K 90, croscarmellose sodium, talc & magnesium stearate.

Capsule Shell composition: Gelatin, sodium lauryl sulfate, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), FD & C Blue 2 (E132)
Black Ink composition: Shellac, Black iron oxide.

What Mycophenolate Mofetil Capsules looks like and content of the pack:
Mycophenolate Mofetil 250 mg capsules are light blue/peach size '1' hard gelatin capsules with imprinting with 'MMF' on cap and '250' on body, containing white to off white powder.

Mycophenolate Mofetil 250 mg Capsules are available in blister in packs of 100 and 300' capsules.

Not all pack sizes may be marketed.

Marketing authorization holder:
Accord Healthcare Limited
Sage House,
319, Pinner Road,
North Harrow,
Middlesex, HA1 4HF,
United Kingdom

Manufacturer:
Accord Healthcare Limited
Sage House,
319, Pinner Road,
North Harrow,
Middlesex, HA1 4HF,
United Kingdom

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare single member S.A.
64th Km National Road Athens, Lamia,
Schimatari, 32009, Greece

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