

Package leaflet: Information for the user

Mycofenolate Mofetil 250 mg capsules, hard

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

1. What Mycofenolate mofetil is and what it is used for

Mycofenolate Mofetil contains mycophenolate mofetil.

- This belongs to a group of medicines called “immune-suppressants”.

Mycofenolate Mofetil is used to prevent your body rejecting a transplanted organ.

- A kidney, heart or liver.

Mycofenolate Mofetil is used together with other medicines:

- ciclosporin
- corticosteroids.

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

Do not take Mycofenolate 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 pregnant or breast-feeding.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Mycofenolate Mofetil.

Warnings and precautions

Talk to your doctor before taking Mycofenolate Mofetil if:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding.
- you have ever had a problem with your digestive system such as a stomach ulcer.
- you are planning to become pregnant or if you get pregnant while taking Mycofenolate Mofetil.

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

The effect of sunlight

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

Other medicines and Mycofenolate Mofetil

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

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

- azathioprine 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
- phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood.

Vaccines

If you need to have a vaccine (a live vaccine) while taking Mycofenolate Mofetil, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

Mycofenolate Mofetil with food and drink

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

Pregnancy, contraception and breast-feeding

Pregnancy

- **If you are pregnant**, do not take Mycofenolate Mofetil. This is because Mycofenolate Mofetil may cause miscarriage or damage to your unborn baby (affecting development of ears for example).
 - In certain situations, you and your doctor may decide that the benefits of taking Mycofenolate Mofetil for your health are more important than the possible risks to your unborn baby.
- **If you plan to become pregnant**, talk to your doctor first. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- **If you think you may be pregnant tell your doctor straight away.**
 - However, keep taking Mycofenolate Mofetil until you see him or her.

If you are able to become pregnant, you must have a pregnancy test before you start Mycofenolate Mofetil. You can only start Mycofenolate Mofetil if the test is negative.

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

You must always 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.

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.

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.

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 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 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 and adolescents (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 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 and adolescents

- 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 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 and adolescents

- There is no information for the use of Mycophenolate Mofetil in children with a liver transplant.

Taking the medicine

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 than you should

If you take more Mycophenolate Mofetil 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 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

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 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, 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 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 Mycophenolate Mofetil 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 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.

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

Do not store above 30°C.

Store in the original package in order to protect from moisture

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 Mycophenolate Mofetil contains

- The active substance is mycophenolate mofetil. Each capsule contains 250 mg mycophenolate mofetil.
- The other ingredients are:
Capsule: microcrystalline cellulose, povidone (K-90), hydroxypropyl cellulose, croscarmellose sodium, talc, magnesium stearate
Capsule shell: gelatine, sodium lauryl sulphate, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), indigo carmine aluminium lake (E132)
Ink: shellac, iron oxide black (E172)

What Mycophenolate Mofetil looks like and contents of the pack

White opaque PVC/PVdC-Aluminium blister pack.

1 carton contains 100 capsules

1 carton contains 300 capsules

Not all pack sizes may be marketed.

Mycophenolate Mofetil 250 mg capsules: light blue/peach, size 1 hard capsule, 18.9 mm ± 0.5 mm in length, imprinted with MMF on cap and 250 on body, containing white to off-white powder.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegur 76 – 78
220 Hafnarfjörður
Iceland

Manufacturer

Actavis Group PTC ehf
Reykjavíkurvegur 76 – 78
220 Hafnarfjörður
Iceland

Actavis Nordic A/S
Ørnegårdsvej 16
2820 Gentofte
Denmark

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

Belgium	Mycophenolaatmofetil Actavis 250 mg capsules, hard
Bulgaria	Mycophenolate mofetil Actavis
Germany	Mykophenolatmofetil/Actavis 250 mg Hartkapseln
Finland	Mycophenolate Mofetil 250 mg, kapseli, kova

France	Mycophenolate mofetil Actavis 250 mg, gélule
Ireland	Mycophenolate mofetil 250mg Capsules
Italy	Micofenolato mofetile Actavis PTC 250 mg capsule
The Netherlands	Mycofenolaat mofetil Actavis 250 mg
Norway	Mycophenolate Mofetil
Portugal	Micofenolato de mofetil Actavis
Sweden	Mycophenolate Mofetil
United Kingdom	Mycophenolate mofetil 250mg Capsules

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