PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Mycophenolate mofetil Tillomed 250 mg

Hard Capsules

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 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 or 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 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
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1. What Mycophenolate mofetil is and what it is used for

Mycophenolate mofetil 250 mg belongs to a group of medicines called "immunosuppressants".

Mycophenolate mofetil is used to prevent your body from rejecting a transplanted kidney, heart or liver.

Mycophenolate mofetil should be used together with other medicines such as ciclosporins and corticosteroids.

The name of your medicine is Mycophenolate mofetil Tillomed 250 mg Hard Capsules, but will be referred to as Mycophenolate mofetil throughout this leaflet.

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

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:

- if you are allergic to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in 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 Mycophenolate mofetil.

Warnings and precautions

Talk to your doctor straight away 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 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 taking 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, which also covers your head, neck, arms and legs,
- using a sunscreen with a high protection factor.

Children

Do not give this medicine to children younger than 2 years because based on the limited safety and efficacy data for this age group no dose recommendations can be made.

Other medicines and Mycophenolate mofetil

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 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 is 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 vaccine (a live vaccine) whilst 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 six 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 with food and drink

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

Contraception

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 an effective method of contraception.

If you do become pregnant during 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 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 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.

Mycophenolate mofetil Tillomed contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule 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.

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.

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 two separate doses.
- Take 4 capsules in the morning and then 4 capsules 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.

Heart transplant

Adults

- The first dose is given within 5 days of the transplant operation.
- The daily dose is 12 caspules (3 g of the medicine) taken as two separate doses.
- Take 6 capsules in the morning and then 6 capsules 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 12 capsules (3 g of the medicine) taken as two separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

Children

- 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 missed 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,
- rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, lightheadedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalised 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.

Children may be more likely than adults to have some side effects. These include diarrhoea, infections and 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 patients on mycophenolate have developed cancer of the lymphoid tissues and skin.

General unwanted side 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 and 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 disorders,
- diarrhoea, constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence.

Nervous system problems such as:
- feeling dizzy, drowsy or numb,
- tremor, muscle spasms, convulsions (fits),
- feeling anxious or depressed, changes in your mood or thoughts.

Heart and blood vessel problems such as:
- change in blood pressure, unusual 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 lungs). 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 and bruising.

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 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 (EXP) and blister. 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 to protect the environment.

6. Contents of the pack and other information

What Mycophenolate mofetil Tillomed 250 mg Hard Capsules contains

- The active substance is mycophenolate mofetil. Each capsule contains 250 mg mycophenolate mofetil.
- The other ingredients are:

Capsule content
Pregelatinised starch
Croscarmellose sodium
Povidone (K 90)
Magnesium stearate

Capsule shell
Gelatin
Indigo carmine (E132)
Titanium dioxide (E171)
Iron oxide red (E172)
Iron oxide yellow (E172)

Printing ink
Shellac
Black iron oxide (E172)
Potassium hydroxide

What Mycophenolate mofetil Tillomed 250 mg Hard Capsules looks like and contents of the pack

Mycophenolate mofetil Tillomed 250 mg Hard Capsules are Size '1 ', two-piece, hard gelatin capsules, with a blue opaque cap and a brown opaque body, with "EM" printed in black on the capsule cap and “250” printed in black on the capsule body, filled with white to off-white granular powder.

Mycophenolate mofetil Tillomed 250 mg Hard Capsules are supplied in 100 x 1 or 300 x 1 capsules in PVC white opaque/aluminium foil perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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