APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MYFENOTIL 250 (CAPSULES)

Mycophenolate Mofetil

Sugar free

WARNING 1: DO NOT TAKE MYFENOTIL 250

If you are pregnant or planning to become pregnant, or breastfeeding your baby, you must not receive MYFENOTIL 250 (see BEFORE YOU TAKE MYFENOTIL 250 and Pregnancy and breastfeeding).

WARNING 2: IMMUNE SYSTEM SUPPRESSED: RISK OF INFECTIONS AND CANCER

Increased likelihood of infection and the possible development of a cancer of the lymph nodes or tissues and other cancers, especially of the skin, may result from the body's immune system being suppressed. Only doctors experienced in medicines which suppress the body's immune response and management of kidney, heart or liver transplant patients should prescribe MYFENOTIL 250. Patients receiving MYFENOTIL 250 should be managed by healthcare professionals experienced in relevant laboratory and medical resources and knowledge. The doctor responsible for your maintenance therapy will have complete information available for your follow-up.

WARNING 3: RISK OF BIRTH DEFECTS

MYFENOTIL 250 can cause malformations and mutations in unborn foetuses. Before birth malformations and spontaneous abortions have been reported with use of MYFENOTIL 250 in pregnancy. Women of childbearing potential must have two negative medical practitioner

or laboratory-supervised blood or urine pregnancy tests; the second test should be performed 8-10 days after the first one and 24 hours before starting treatment with MYFENOTIL 250. Repeat pregnancy tests should be performed during routine follow-up visits. Women of childbearing potential should use two reliable forms of birth control simultaneously, including at least one highly effective method, before beginning MYFENOTIL 250 therapy, during therapy, and for 90 days following discontinuation of therapy; unless not having intercourse is the chosen method of birth control. Sexually active men are recommended to use condoms during treatment and for 90 days after stopping treatment. Condom use applies both for reproductively able men and men who have had a vasectomy, because the risk associated with the transfer of semen also applies to men who have had a vasectomy. Female partners of male patients are recommended to use highly effective birth control methods during treatment and for a total of 90 days after the last dose of MYFENOTIL 250.

Read all of this leaflet carefully before you start taking MYFENOTIL 250

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MYFENOTIL 250 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYFENOTIL 250 is and what it is used for
2. What you need to know before you take MYFENOTIL 250
3. How to take MYFENOTIL 250
4. Possible side effects

5. How to store MYFENOTIL 250

6. Contents of the pack and other information

1. What MYFENOTIL 250 is and what it is used for

The active ingredient in MYFENOTIL 250 is mycophenolate mofetil. MYFENOTIL 250 belongs to a group of medicines called “immunosuppressants”. MYFENOTIL 250 is used to prevent your body rejecting a transplanted organ, i.e., kidney, heart or liver. MYFENOTIL 250 should be used together with other medicines such as ciclosporin and corticosteroids.

2. What you need to know before you take MYFENOTIL 250

Do not take MYFENOTIL 250:

- If you are hypersensitive (allergic) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant, planning to become pregnant or think you may be pregnant.
- If you are breastfeeding.
- If you are not using highly effective contraception.
- If you have Lesch-Nyhan or Kelley-Seegmiller syndrome or another rare inherited deficiency hypoxanthine-guanine phosphoribosyl-transferase (HGPRT). You should not take MYFENOTIL 250 if you have one of these disorders.

Warnings and precautions

Take special care with MYFENOTIL 250:

- MYFENOTIL 250 reduces your body’s defences. As a result, there is an increased risk of cancers, especially skin cancer. Limit the amount of sunlight and UV light you get. Therefore, wear protective clothing that also covers your head, neck, arms and legs and use a sunscreen with a high protection factor.

- If you experience any evidence of infection (e.g., fever, sore throat), unexpected bruising and/or bleeding.
- If you have or have ever had any problems with your digestive system, e.g., stomach ulcers.
- If you are planning to become pregnant or if you get pregnant while you or your partner are taking MYFENOTIL 250.
- If you need to have a vaccination (a live vaccine) while taking MYFENOTIL 250, 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 MYFENOTIL 250 and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with MYFENOTIL 250 and for at least 90 days after stopping treatment.
- If you suffer from chronic kidney impairment.
- If you are over 65 years old.
- If you suffer from cough and shortness of breath.

Children

Children particularly under 6 years of age are prone to treatment-related adverse events such as diarrhoea, sepsis, low white blood cell count, anaemia and infection.

Other medicines and MYFENOTIL 250

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please inform your health care provider if you are currently taking any of the following medicines listed below:

- 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 including lansoprazole and pantoprazole, 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.
- Antibiotic (ciprofloxacin or amoxicillin plus clavulanic acid, metronidazole), used to treat bacterial infections.
- Isavuconazole, used to treat fungal infections.
- Telmisartan, used to treat high blood pressure.
- Tacrolimus, used to treat viral infections.
- Sirolimus, used for prevention of renal transplant rejection.
- Belatacept, used for prevention of renal transplant rejection.
- Acyclovir, used to prevent or treat viral infections.
- Sevelamer, used to treat hyperphosphatemia, too much phosphate in the blood.
- Probenecid, used to manage too much uric acid in your blood.
- Any other medicines (including those you can buy without a prescription) that your doctor does not know about.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MYFENOTIL 250.

Women of childbearing potential

If you are a woman who could become pregnant, you must use an effective method of contraception with MYFENOTIL 250. This includes:

- Before you start taking MYFENOTIL 250.
- During your entire treatment with MYFENOTIL 250.
- For 6 weeks after you stop taking MYFENOTIL 250.

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.

Pregnancy

Do not take MYFENOTIL 250 if you are pregnant.

If you could possibly become pregnant, you must have a pregnancy test with a negative result BEFORE starting treatment with MYFENOTIL 250.

The use of MYFENOTIL 250 during pregnancy may cause miscarriage or damage to your unborn baby (abnormal development). 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 plan to become pregnant, discuss with your doctor alternative medicines to best prevent rejection of your transplanted organ.

Tell your doctor straight away if:

- You plan to start a family in the near future.
- You missed or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.

- You had sex without using effective methods of contraception.

Breastfeeding

Do not take MYFENOTIL 250 if you are breastfeeding. This is because small amounts of the medicine can pass into the mother's milk.

Contraception in men taking MYFENOTIL 250

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 MYFENOTIL 250. If you are planning to have a child, talk to your doctor about the potential risks and alternative therapies.

Driving and using machines

It is not always possible to predict to what extent MYFENOTIL 250 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYFENOTIL 250 affects them.

MYFENOTIL 250 has a moderate influence on your ability to drive or use any tools or machines. If you feel drowsy, numb, confused, tremor or hypotension, talk to your doctor or nurse and do not drive or use any tools or machines until you feel better.

3. How to take MYFENOTIL 250

Do not share medicines prescribed for you with any other person.

Always take MYFENOTIL 250 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You have to be careful when handling your capsules. Do not break or crush them. You should swallow them whole whenever possible. If you accidentally touch damaged capsules, wash your hands thoroughly with soap and water. If any powder from the capsules gets in your eyes, rinse your eyes with sterile water or clean water if you do not have sterile water.

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 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 (aged 3 months 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 should be taken twice a day.

Heart transplant

Adults

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

There is no information for the use of MYFENOTIL 250 in children with a heart transplant.

Liver transplant

Adults

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

There is no information for the use of MYFENOTIL 250 in children with a liver transplant.

Your doctor will tell you how long your treatment with MYFENOTIL 250 will last. Do not stop your treatment with MYFENOTIL 250 unless your doctor tells you to. If you have the impression that the effect of MYFENOTIL 250 is too strong or too weak, tell your doctor or pharmacist.

If you take more MYFENOTIL 250 than you should

In the event of overdosage, consult your doctor, pharmacist or nurse. If neither is available, contact the nearest hospital or poison centre.

Contact your doctor or hospital immediately if you have taken or think you have taken more MYFENOTIL 250 than you should. Taking too much MYFENOTIL 250 can cause serious side effects. You may need hospital treatment.

If you forget to take MYFENOTIL 250

It is important that you continue to take your medicine according to the instructions on the label and that you do not miss any doses. However, if you forget to take a dose, take it as soon as you remember (unless it is nearly time for your next dose, in which case leave out the missed dose). Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYFENOTIL 250

Do not stop your treatment with MYFENOTIL 250 unless your doctor tells you to. If you stop your treatment, you may increase the chance of rejection of your transplant organ.

4. Possible side effects

MYFENOTIL 250 can have side effects.

Not all side effects reported for MYFENOTIL 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYFENOTIL 250, please inform your health care provider for advice.

If any of the following happens, stop taking MYFENOTIL 250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A raised, itchy skin rash (hives).
- Sudden swelling of the throat, face, lips and mouth which may cause difficulty swallowing or breathing.
- Sudden swelling of the hands, feet or ankles.
- Fainting.
- Signs of infection such as a fever or sore throat.
- Any unexpected bruising or bleeding.
- Fewer white cells or red cells in your blood (Your doctor will do regular blood tests to check for any changes in the number of your blood cells or signs of infections).
- Abnormal skin lesions or lymph tissue growth.
- Diarrhoea and vomiting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYFENOTIL 250. You may need urgent medical attention.

The side effects that have occurred during treatment with MYFENOTIL 250 are given below. Tell your doctor if you notice any of the following:

Frequent side effects:	Less frequent side effects:
• Bacterial infections • Fungal infections • Viral infections • Benign abnormal mass of tissue of skin • Abnormal mass of tissue that forms when cells grow and divide more than they should • Skin cancer • Low red blood cells or hemoglobin • Discoloration of the skin resulting from bleeding underneath • High white blood cell count • Low white blood cell count • Lower-than-normal number of red and white blood cells and platelets in the blood	• Protozoal infections • Cancer of the lymphatic system • Lymphoproliferative disorder • Rare blood disorder that happens when your bone marrow doesn't produce the normal number of red blood cells • Bone marrow failure • Conditions that simulate a lymphoma (blood cell cancer), but behave in a harmless manner • Agitation • Thinking abnormal • Taste disorder • Collection of lymphatic fluid within the body not bordered by epithelial lining • Long-term condition where the airways of the lungs become widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection • Interstitial lung disease • Pulmonary fibrosis

• Low platelet count • Body fluids contain too much acid • High cholesterol • High blood sugar • High potassium levels • High lipids (fats) in your blood • Low calcium levels • Low magnesium levels • Low phosphate levels • High uric acid levels • Gout • Weight decreased • Confusion • Depression • Sleeplessness • Anxiety • Dizziness • Headache • Too much muscle tone • Burning or prickling sensation • Drowsiness • Tremors • Fits • Fast heart rate	• Inflammation of pancreas • Hypersensitivity • Low serum immunoglobulin or antibody levels • Jaundice • Blood urea increased • De novo purine synthesis inhibitors associated acute inflammatory syndrome

• High blood pressure • Low blood pressure • Venous blood clots • Dilation of veins • Cough • Shortness of breath • Water on the lungs • Abdominal distension • Abdominal pain • Inflammation in your colon • Constipation • Decreased appetite • Diarrhoea • Indigestion • Inflammation of the oesophagus • Belching • Flatulence • Inflammation of the lining of the stomach • Gastrointestinal bleeding • Gastrointestinal ulcers • Overgrown gums • Lack of movement somewhere in the intestines • Mouth ulceration	

• Nausea • Inflamed and sore mouth • Vomiting • Blood alkaline phosphatase increased • Blood lactate dehydrogenase increased • Hepatic enzyme increased • Jaundice • High bilirubin levels • Acne • Hairloss • Rash • Skin overgrowth • Joint pain • Muscular weakness • Blood creatinine increased • Blood urea increased • Blood in urine • Renal impairment • Weakness • Chills • Swelling • Hernia • Tiredness • Pain	

• Fever	

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or nurse.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MYFENOTIL 250.

5. How to store MYFENOTIL 250

Store all medicines out of sight and reach of children.

Store at or below 25 ºC (room temperature).

Store in the original container in order to protect form light and moisture.

Do not break or crush the capsules. Avoid contact of broken or crushed capsules. Avoid inhalation, or direct contact with skin or mucous membranes, of the powder contained in MYFENOTIL 250 capsules. If such contact occurs, wash thoroughly with soap and water, rinse eyes with plain water.

Do not take MYFENOTIL 250 after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MYFENOTIL 250 contains

The active substance is mycophenolate mofetil. Each capsule contains 250 mg of mycophenolate mofetil.

The other ingredients are:

Filling:

Microcrystalline cellulose (Avicel-PH 101)

Croscarmellose sodium (AC-DI-SOL)

Povidone (K-30)

Magnesium stearate

Capsule (Cap and Body):

Gelatine

Titanium dioxide (E171)

Iron oxide yellow (E172)

FD & C Red 3 (E127)

What MYFENOTIL 250 looks like

MYFENOTIL 250 capsules are a white to off white blend of mycophenolate mofetil filled in size 1 hard gelatine capsules with ivory cap and ivory body printed "SAL" on cap and "726" on body in black.

MYFENOTIL 250 is packed in white opaque HDPE containers with ribbed screw white opaque polypropylene closures.

Pack sizes: 100, 120 or 500.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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Fourth Floor

Sandton

Gauteng

South Africa

2031

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