Teva Pharmaceuticals (Pty) Ltd	**Product:** Mycophenolate Teva 250 mg capsules and 500 mg tablets
	MYCOPHENOLATE TEVA 500: 45/32.16/1086 MYCOPHENOLATE TEVA 250: 46/32.16/0322
Date of Registration: 11 June 2018	**SAHPRA approval date: 26.05.2026**

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

MYCOPHENOLATE TEVA 500 (film-coated tablets)

MYCOPHENOLATE TEVA 250 (capsules)

Mycophenolate mofetil

Sugar free

Read all of this leaflet carefully before you start using MYCOPHENOLATE TEVA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MYCOPHENOLATE TEVA 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 MYCOPHENOLATE TEVA IS AND WHAT IT IS USED FOR:

MYCOPHENOLATE TEVA is used to prevent your body rejecting a transplanted kidney, heart or liver. It is used together with other medicines with a similar function such as ciclosporin and corticosteroids.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MYCOPHENOLATE TEVA:

Follow your doctor's instructions carefully. They may differ from the general instructions in this leaflet.

MYCOPHENOLATE TEVA causes birth defects and miscarriage; therefore precautions must be taken to prevent pregnancy with MYCOPHENOLATE TEVA.

If you are a woman who could become pregnant, you must have a negative pregnancy test before starting treatment with MYCOPHENOLATE TEVA. You should also use effective contraception as advised by your doctor.

Male patients should use condoms and their female partners should use contraception as advised by your doctor. (See **Pregnancy and breastfeeding**).

Do not take MYCOPHENOLATE TEVA:

- if you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients of MYCOPHENOLATE TEVA
- if you are pregnant or breastfeeding your baby, (see **Pregnancy and breastfeeding**).

Warnings and precautions:

Take special care with MYCOPHENOLATE TEVA:

When you are treated with MYCOPHENOLATE TEVA you have an increased risk of developing lymphomas and other malignancies (cancer), particularly of your skin. To minimise any risk of skin cancer you should limit exposure to sunlight and UV light by wearing protective clothing and using sunscreen with a high protection factor.

Inform your doctor before taking MYCOPHENOLATE TEVA if:

- you experience any evidence of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding
- you ever have or have had any problems with your digestive system for example stomach ulcers
- you have a rare hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan and Kelley-Seegmillar syndrome (which causes kidney problems and gout characterised by painful swelling of the foot)
- you have severe kidney problems
- you are taking other medicines to suppress your immune system such as azathioprine (see **Other medicines and MYCOPHENOLATE TEVA**)
- you are over 65 years old.

Inform your doctor if you develop shortness of breath or a persistent cough while taking MYCOPHENOLATE TEVA, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lung).

Inform your doctor if you experience fatigue, lethargy and/or abnormal paleness of the skin (pallor) while taking MYCOPHENOLATE TEVA.

Inform your doctor if you get infected with Covid-19 while taking MYCOPHENOLATE TEVA.

You must not donate blood during treatment with MYCOPHENOLATE TEVA and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with MYCOPHENOLATE TEVA and for at least 90 days after stopping treatment.

Other medicines and MYCOPHENOLATE TEVA:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor if you are taking:

- any medicines such as azathioprine or tacrolimus used to suppress your immune system (which are sometimes given to patients after a transplant operation)
- antiviral medicines such as aciclovir or ganciclovir
- medicines used to treat indigestion or heartburn such as proton pump inhibitors or antacids with magnesium and aluminium hydroxide
- cholestyramine (used to treat high cholesterol)
- rifampicin (an antibiotic used to treat tuberculosis)
- antibiotics such as ciprofloxacin, amoxicillin plus clavulanic acid or the combination of norfloxacin and metronidazole
- probenecid (a medicine used to treat gout) or phosphate binders (a medicine used for chronic kidney failure to reduce how much phosphate gets absorbed into the blood)
- telmisartan (a medicine used to reduce blood pressure)
- isavuconazole (used to treat fungal infections)
- phosphate binders such as sevelamer (used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood)
- if you need to receive vaccines, especially live vaccines.

Taking MYCOPHENOLATE TEVA with food and drink:

Taking food and drink has no influence on your treatment with MYCOPHENOLATE TEVA.

Pregnancy and breastfeeding:

Do not take MYCOPHENOLATE TEVA if you are pregnant or breastfeeding your baby.

MYCOPHENOLATE TEVA causes birth defects and miscarriage, therefore precautions must be taken to prevent pregnancy with MYCOPHENOLATE TEVA treatment.

If you are a woman who could become pregnant, you must have a negative pregnancy test before starting treatment with MYCOPHENOLATE TEVA. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

You should also use two forms of contraception simultaneously before beginning treatment with MYCOPHENOLATE TEVA, during treatment and for six weeks after stopping MYCOPHENOLATE TEVA treatment.

Sexually active males (including males who have had a vasectomy) should use condoms during treatment with MYCOPHENOLATE TEVA and for at least 90 days after stopping MYCOPHENOLATE TEVA treatment.

Female partners of male patients should use contraception during treatment and for 90 days after stopping MYCOPHENOLATE TEVA.

Breastfeeding:

Do not take MYCOPHENOLATE TEVA if you are breastfeeding. This is because small amounts of the medicine can pass into the mother’s milk.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MYCOPHENOLATE TEVA.

Tell your doctor immediately if you become pregnant or if you plan to start a family in the near future while taking MYCOPHENOLATE TEVA.

Driving and using machines:

MYCOPHENOLATE TEVA may make you feel dizzy, sleepy, confused or can cause tremors (shaky hands) and low blood pressure, therefore you should not engage in activities such as driving or operating machinery until you know how MYCOPHENOLATE TEVA affects you.

3. HOW TO USE MYCOPHENOLATE TEVA:

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

Always take MYCOPHENOLATE TEVA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of MYCOPHENOLATE TEVA is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will determine your dose according to your condition.

How to take MYCOPHENOLATE TEVA 500:

MYCOPHENOLATE TEVA 500 tablets should be taken on an empty stomach (i.e. 1 hour before or 3 hours after food).

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

How to take MYCOPHENOLATE TEVA 250:

MYCOPHENOLATE TEVA 250 capsules should be taken on an empty stomach (i.e. 1 hour before or 3 hours after food).

Swallow your capsules whole with a glass of water. Do not break or crush them and do not take any capsules that have broken open or split. Avoid contact with any powder that spills out from damaged capsules. If a capsule breaks open accidentally, wash any powder from your skin with soap and water. If any powder gets into your eyes or mouth, rinse thoroughly with water.

Your doctor will tell you exactly how long you will need to take MYCOPHENOLATE TEVA tablets or capsules. Treatment with MYCOPHENOLATE TEVA will continue for as long as your immune system

needs to be suppressed to prevent your body from rejecting your transplanted organ.

If you take more MYCOPHENOLATE TEVA than you should:

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

If you forget to take MYCOPHENOLATE TEVA:

If you forget to take a dose of MYCOPHENOLATE TEVA, take it as soon as you remember, then carry on with the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYCOPHENOLATE TEVA:

Do not stop taking MYCOPHENOLATE TEVA because you feel better. It is important to take MYCOPHENOLATE TEVA for as long as the doctor has told you to. Stopping your treatment with MYCOPHENOLATE TEVA may increase the chance of rejection of your transplanted organ. Do not stop taking MYCOPHENOLATE TEVA unless your doctor tells you to.

If you have any further questions on the use of MYCOPHENOLATE TEVA, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

MYCOPHENOLATE TEVA can have side effects.

Not all side effects reported for MYCOPHENOLATE TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYCOPHENOLATE TEVA, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to

MYCOPHENOLATE TEVA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- signs of infection or flu-like symptoms such as a fever or sore throat, as well as infections of the chest, stomach, bladder, mouth, skin or vagina
- any unexpected bruising or bleeding, weakness, breathlessness
- blood in your stools or urine
- growths of the skin or changes in your skin
- convulsions, increased tension in the muscles, shaking and muscle weakness
- severe chest pain, irregular heartbeat
- yellowing of the skin and eyes
- difficulty passing urine, decreased or frequent urination
- swelling of your body.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following which may occur frequently:

- high blood sugar (causes thirst and frequent urination), gout (painful, swelling of the feet), dehydration
- agitation, confusion, depression, anxiety, abnormal thinking, difficulty sleeping, hallucinations, changes in your mood or thoughts
- drowsiness, dizziness, headache, pins and needles, taste disturbances
- blurred or abnormal vision, eye infection, burst vessel in the eye
- ear pain, loss of hearing, ringing in the ears
- high or low blood pressure (causes headaches or fainting), blood clots
- cough, asthma (tight chest), shortness of breath
- nausea (feeling sick), vomiting, stomach pain, diarrhoea (loose stools), constipation, indigestion, flatulence, swollen stomach, mouth sores, difficulty swallowing, decreased appetite
- rash, acne (pimples), hair loss, sweating, excessive hair growth, sores on the skin, swollen face
- joint pain, pelvic pain, neck pain, leg cramps, muscle pain, back pain, muscle weakness

- difficulty in maintaining an erection
- feeling ill, lack of energy, pale skin
- changes in your weight.

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MYCOPHENOLATE TEVA.

5. HOW TO STORE MYCOPHENOLATE TEVA:

Store at or below 25 °C.

Keep in the original package and protect from light and moisture.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Because mycophenolate mofetil has demonstrated teratogenic effects in rats and rabbits, MYCOPHENOLATE TEVA capsules and tablets should not be opened or crushed. Avoid inhalation, or direct contact with skin or mucous membranes, of the powder contained in MYCOPHENOLATE TEVA capsules. If such contact occurs, wash thoroughly with soap and water, rinse eyes with plain water.

Do not take MYCOPHENOLATE TEVA after the expiry date shown on the pack.

Do not use any MYCOPHENOLATE TEVA from a pack that is damaged or shows signs of tampering.

Return all unused medicine 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 MYCOPHENOLATE TEVA contains:

MYCOPHENOLATE TEVA 500: Each film-coated tablet contains the active substance mycophenolate mofetil 500 mg.

MYCOPHENOLATE TEVA 250: Each capsule contains the active substance mycophenolate mofetil 250 mg.

The other ingredients are:

MYCOPHENOLATE TEVA 500: croscarmellose sodium, magnesium stearate, microcrystalline cellulose and povidone.

The tablet coating Opadry purple consists of: hypromellose 6cP, indigo carmine aluminium lake FD&C blue (E132), iron oxide black (E172), iron oxide red (E172), polyethylene glycol, talc and titanium dioxide.

MYCOPHENOLATE TEVA 250: croscarmellose sodium, magnesium stearate, povidone, pregelatinised starch.

The capsule shell cap consists of: indigo carmine (E132), titanium dioxide (E171), gelatin and the capsule shell body consists of red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171) and gelatin.

Black ink containing shellac, black iron oxide (E172), propylene glycol and potassium hydroxide.

What MYCOPHENOLATE TEVA looks like and contents of the pack:

MYCOPHENOLATE TEVA 500: Pale purple, oval shaped film-coated tablet, debossed with 'M500' on one side and plain on the other side.

MYCOPHENOLATE TEVA 250: Hard gelatin capsule size 1, filled with a white to off-white powder. Cap: light blue opaque printed 'M' axially in black ink. Body: caramel opaque, printed '250' axially in black ink.

Contents of the pack:

MYCOPHENOLATE TEVA 500:

Transparent PVC/PVDC-aluminium blisters. Each blister strip contains 10 tablets.

Pack size 50: 5 blister strips packed in an outer carton.

Pack size 150: 15 blister strips packed in an outer carton.

MYCOPHENOLATE TEVA 250:

Transparent PVC/PVDC-aluminium blisters. Each blister strip contains 10 capsules.

Pack size 100: 10 blister strips packed in an outer carton.

Pack size 300: 30 blister strips packed in an outer carton.

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Date of Registration: 11 June 2018	**SAHPRA approval date: 26.05.2026**

Holder of Certificate of Registration:

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This leaflet was last revised in:

26 May 2026

Registration numbers:

MYCOPHENOLATE TEVA 500: 45/32.16/1086

MYCOPHENOLATE TEVA 250: 46/32.16/0322

Access to the corresponding Professional Information:

Website: https://www.teva.co.za/

The Professional Information can also be obtained from:

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