NOVARTIS

MYFORTIC® 180 mg / 360 mg

TABLETS

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Myfortic® 180 tablet

Myfortic® 360 tablet

Mycophenolic acid (as sodium salt) 180 mg, 360 mg

Contains sugar:

Myfortic® 180: Lactose 45,0 mg

Myfortic ® 360: Lactose 90,0 mg

WARNING 1: DO NOT TAKE

If you are pregnant or planning to become pregnant, or breastfeeding your baby, you must not take MYFORTIC (see **Pregnancy and breastfeeding and fertility)**

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 MYFORTIC. Patients receiving MYFORTIC 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

MYFORTIC can cause malformations and mutations in unborn foetuses. Before birth malformations and spontaneous abortions have been reported with use of MYFORTIC 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 MYFORTIC. 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 MYFORTIC 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 MYFORTIC.

Read all of this leaflet carefully before you start taking MYFORTIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MYFORTIC 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 MYFORTIC is and what it is used for.
2. What you need to know before you take MYFORTIC.
3. How to take MYFORTIC.
4. Possible side effects.
5. How to store MYFORTIC.
6. Contents of the pack and other information.

1. What MYFORTIC is and what it is used for

What MYFORTIC is:

MYFORTIC tablets belong to the class of medicines known as immunosuppressants. Immunosuppressants reduce your body’s response to anything that it sees as “foreign” – which includes transplanted organs.

What MYFORTIC is used for

MYFORTIC is used to prevent your body from rejecting a transplanted kidney. MYFORTIC is used together with other medicines containing ciclosporin and corticosteroids.

If you have any questions about how MYFORTIC works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take MYFORTIC

MYFORTIC will only be prescribed for you by a doctor with experience in transplantation medicine. Follow your doctor's instructions carefully.

Do not take MYFORTIC:

- If you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium or mycophenolate mofetil or to any of the other ingredients of MYFORTIC listed at the beginning of this leaflet.
- If you think you may be allergic, ask your doctor for advice.
- 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.
- If you are breast-feeding.

Warnings and precautions

Take special care with MYFORTIC:

- During exposure to sunlight;
- MYFORTIC reduces your body's defence mechanism, causing an increased risk of skin cancer. You should therefore limit your exposure to sunlight and UV light by wearing appropriate protective clothing and frequently applying a sunscreen with a high protection factor;
- If you already had hepatitis B or C MYFORTIC may increase the risk of these diseases re-appearing. Your doctor may perform blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) you should inform your doctor immediately;
- If you experience any symptoms of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding. In such cases you should inform your doctor immediately;
- If you need to receive vaccines (live vaccines). Seek your doctor's advice first;
- If you have, or have ever had, a serious disorder of the digestive tract, e.g. stomach ulcer;
- If you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan syndrome (also known as Kelley-Seegmiller syndrome);

- If you are a woman of childbearing age: treatment with MYFORTIC should not be initiated until a negative pregnancy test has been obtained and you should use contraception during treatment and for at least 6 weeks after stopping the treatment;
- Use of MYFORTIC in pregnancy may increase the risk of birth defects and pregnancy loss including spontaneous abortion (see section Pregnancy and breastfeeding and fertility

If any of these apply to you, tell your doctor before you take MYFORTIC.

MYFORTIC and older people:

- MYFORTIC can be given to the elderly.
- No dose adjustment is required.

Children and adolescents:

- Safety and efficacy in children have not been established.

Other medicines and MYFORTIC

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines (this includes complementary or traditional medicines).

Remember to mention those you have bought without a prescription to your doctor; this includes antacids (medicines used to treat dyspepsia and heartburn).

It is particularly important that you tell your doctor if you are taking any of the following medicines:

- Azathioprine, or any other immunosuppressive agent.
- Cholestyramine (a medicine used to treat high blood cholesterol levels).
- Aciclovir (a medicine used to treat herpes infection).
- Ganciclovir (a medicine used to treat cytomegalovirus [CMV] infection).
- Before administration of live attenuated vaccines.
- Oral contraceptives.

MYFORTIC with food and drink and alcohol

MYFORTIC can be taken with or without food.

Pregnancy and breastfeeding and fertility

- MYFORTIC should not be used during pregnancy.
- If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.
- If you are pregnant or think you may be pregnant, tell your doctor.
- Your doctor will discuss with you the potential risks of taking MYFORTIC during pregnancy.
- Women who could become pregnant are advised to use an effective method of contraception during treatment and for 6 weeks after they have stopped

taking MYFORTIC.

- If you are breastfeeding, tell your doctor. Do not breastfeed during treatment with MYFORTIC and for 6 weeks after you have stopped taking MYFORTIC.

Men:

If you are a sexually active man, you should use condoms during treatment with MYFORTIC and for 13 weeks after stopping the treatment. Your partner should also use effective contraception during your treatment and for 13 weeks after you have stopped MYFORTIC. Tell your doctor straight away if your partner becomes pregnant while you are taking MYFORTIC.
Men should not donate semen during therapy and for 90 days following discontinuation of MYFORTIC.

Driving and using machinery

MYFORTIC has minor influence on psychomotor performance, but may cause dizziness. It is not always possible to predict to what extent MYFORTIC may interfere with the daily activities of a patient. Patients should ensure that they do not drive or operate machinery engage in the above activities until they are aware of the measure to which MYFORTIC affects them.

Myfortic contains sodium

MYFORTIC contains 13 / 26 mg of sodium (main component of cooking/table salt) in

each Myfortic 180 / 360 mg tablet. This is equivalent to 0,65 / 1,3 % of the recommended maximum daily dietary intake of sodium for an adult.

MYFORTIC contains lactose

MYFORTIC tablets contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take MYFORTIC.

3. How to take MYFORTIC

Do not share medicines prescribed for you with others.

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

Do not exceed the recommended dosage.

The usual dose is:

How much to take:

- The recommended daily dose is 1 440 mg (8 tablets of MYFORTIC 180 mg or 4 tablets of MYFORTIC 360 mg), taken as 2 separate doses of 720 mg each.
- This means taking 4 tablets of MYFORTIC 180 mg or 2 tablets of MYFORTIC 360 mg in the morning and 4 tablets of MYFORTIC 180 mg or 2 tablets of MYFORTIC 360 mg in the evening.
- The first dose of 720 mg will be given within 48 hours after transplantation.

- Your doctor will tell you exactly how many MYFORTIC tablets to take.
- If you have the impression that the effect of MYFORTIC is too strong or too weak, talk to your doctor or pharmacist.

When and how to take MYFORTIC:

- Swallow the tablets whole with a glass of water.
- Do not break or crush them and do not take any tablets that are broken or split.

How long to take MYFORTIC:

- Treatment will continue for as long as you need immunosuppression to prevent you rejecting your transplanted kidney.

If you take more MYFORTIC than you should:

- If you have accidentally taken too many tablets, talk to your doctor straight away. You may require medical attention.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take MYFORTIC:

- Do not take a double dose to make up for forgotten individual doses.

- If you forget to take MYFORTIC, take it as soon as you remember, then continue to take it at the usual times.
- Ask your doctor for advice.

Effects when treatment with MYFORTIC is stopped:

- Stopping your treatment with MYFORTIC may increase the risk of your transplanted organ being rejected.
- Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

MYFORTIC can have side effects.

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

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

- If you experience rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalised itching, skin reddening and facial/throat swelling. These are symptoms of severe allergic reactions;

- If you experience vision changes, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what others say, and muscle weakness. These can be the signs and symptoms of an infection of the brain called progressive multifocal leukoencephalopathy;
- If you have enlarged glands, new or enlarging skin growths, or a change in an existing mole. As can happen in patients taking immunosuppressive medication, a very small number of MYFORTIC patients have developed cancer of the skin or lymph nodes;
- If you have symptoms of infection including fever, chills, sweating, feelings of tiredness, drowsiness, or lack of energy. If you are taking MYFORTIC you may be more susceptible to infections than usual. These may affect various body systems, the most common being the urinary tract, the respiratory tract and the skin;
- If you experience unusual tiredness, headache, shortness of breath with exercise or at rest, dizziness, chest pain, looking pale. These are all symptoms of anaemia (decrease in red blood cells).

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

Tell your doctor if you notice any of the following:

Very common: may affect more than 1 in 10 people

- a reduction in the number of white blood cells;

- reduced level of calcium in the blood, sometimes leading to cramps, (hypocalcaemia);
- muscle weakness, muscle spasms, abnormal heart rhythm (possible symptoms of low level of potassium in the blood) (hypokalaemia);
- abnormal blood test results (high level of uric acid in the blood) (hyperuricaemia);
- headache, dizziness (possible symptoms of high blood pressure) (hypertension);
- dizziness, light-headedness (possible symptoms of low blood pressure) (hypotension);
- infections;
- diarrhoea.

Common: may affect up to 1 in every 10 people:

- bleeding or bruising more easily than normal (signs of low level of platelets);
- muscle spasms, abnormal heart rhythm (possible symptoms of high level of potassium in the blood) (hyperkalaemia);
- abnormal blood test results (low level of magnesium in the blood) (hypomagnesaemia);
- excessive emotional distress, troubled (symptoms of anxiety);
- dizziness;
- headache;

- headache, dizziness, possibly with nausea (possible symptoms of severe high blood pressure) (aggravated hypertension);
- cough;
- shortness of breath, laboured breathing (possible symptoms of dyspnoea or exertional dyspnoea).
- pain (e.g. in the abdomen, stomach);
- constipation;
- indigestion;
- flatulence;
- feeling bloated;
- loose stools;
- nausea;
- vomiting;
- tiredness;
- fever;
- abnormal results of liver or kidney tests;
- pain in joints (arthralgia);
- weakness (asthenia);
- muscle pain (myalgia);
- swollen hands, ankles or feet (possible symptoms of peripheral oedema).

Your doctor will perform regular blood tests to monitor any changes in the number of your blood cells or in the levels of any of the substances carried in your blood, e.g. sugar, fat, and cholesterol.

Uncommon: may affect up to 1 in every 100 people:

- wound infection;
- bone infection;
- cyst containing lymph fluid;
- loss of appetite;
- high levels of fats such as cholesterol and triglycerides (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or low levels of phosphate (hypophosphatemia) in the blood;
- false belief;
- difficulty in sleeping, shakiness;
- discharge of the eye with itching, redness and swelling (conjunctivitis), vision blurred;
- fast heartbeat;
- cough, difficulty breathing, painful breathing (possible symptoms of interstitial lung disease including fatal pulmonary fibrosis);
- fluid build up in the lungs, making it difficult to breathe (pulmonary congestion);
- whistling sound when breathing;

- tenderness in the belly;
- belching;
- bad breath;
- bowel obstruction;
- inflammation of the oesophagus;
- bloody or black stools;
- dry mouth;
- lip lesions;
- salivary glands blockage;
- heartburn;
- inflammation of the gums;
- inflammation of the lining of the abdominal cavity;
- hair loss;
- bruise of the skin;
- acne;
- back pain;
- muscle pain;
- kidney disorders, abnormal narrowing of the tube through which urine passes to the outside of the body, blood in the urine;
- flu-like symptoms, chills;
- swelling of ankles and feet.

Not known: Frequency cannot be estimated from the available data:

- rash;
- fever, pain in joints, swelling of the joints (de novo purine synthesis inhibitors-associated acute inflammatory syndrome).

Additional side effects have been reported with the class of medicines which MYFORTIC belongs to:

- inflammation of the colon or of the oesophagus;
- abdominal pain, vomiting, loss of appetite, nausea (inflammation of the pancreas);
- intestinal perforation;
- stomach or intestine bleeding;
- stomach pain with or without bloody or black stools;
- bowel obstruction;
- serious infections such as inflammation of the heart and its valves and of the membrane that covers the brain and spinal cord, inflammation of lungs;
- reduction in the number of specific white blood cells or of all blood cells;
- fever, sore throat, frequent infections (possible symptoms of lack of white cells in the blood) (agranulocytosis).

If you notice any other side effects not mentioned in this leaflet, please inform your doctor. However, do not stop MYFORTIC tablets unless you have discussed this with your doctor first.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via 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 MYFORTIC.

5. How to store MYFORTIC

- Do not store MYFORTIC above 30 °C.
- Store MYFORTIC in the original package.
- Do not use MYFORTIC after the expiry date printed on the box.
- Do not use any MYFORTIC pack that is damaged or shows signs of tampering.
- Return all unused MYFORTIC to your pharmacist.
- Do not dispose of unused MYFORTIC in drains or sewerage systems.
- Store all medicines out of reach of children.
- Do not store in a bathroom.

6. Contents of the pack and other information

What MYFORTIC contains:

The active substance is:

Each tablet of MYFORTIC 180 contains 180 mg of the active substance mycophenolic acid as sodium salt.

The other ingredients of MYFORTIC 180 are**:**

Tablet core: maize starch, povidone (K-30), crospovidone, lactose, colloidal silicon dioxide, magnesium stearate.

Tablet coating: hypromellose phthalate/hydroxypropylmethylcellulose phthalate, titanium dioxide, iron oxide yellow, indigotine.

Contains sugar:

MYFORTIC 180: Lactose 45,0 mg

The active substance is:

Each tablet of MYFORTIC 360 contains 360 mg of the active substance mycophenolic acid as sodium salt.

The other ingredients of MYFORTIC 360 are:

Tablet core: maize starch, povidone (K-30), crospovidone, lactose, colloidal silicon dioxide, magnesium stearate.

Tablet coating: hypromellose phthalate/hydroxypropylmethylcellulose phthalate, titanium dioxide, iron oxide yellow, iron oxide red.

Contains sugar:

MYFORTIC 360: Lactose 90,0 mg

What MYFORTIC looks like and contents of the pack

Contents of the pack:

The tablets are packed in PA/AL/PVC (polyamide/ aluminium/ polyvinylchloride) and aluminium foil blister packs of 20's, 50's, 100's, 120's or 250's. The outer carton is a printed cardboard box.

Not all pack sizes may be marketed.

What MYFORTIC looks like:

MYFORTIC® 180: Lime green, round, bevelled edged film/enteric-coated tablet marked "C" on the one side.

MYFORTIC® 360: Pale orange-red, ovaloid film/enteric-coated tablet marked "CT" on the one side.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

MYFORTIC® 180	
Namibia: 15/34/0073	NS2
Botswana: BOT1101803A	S2
MYFORTIC® 360	
Namibia: 15/34/0074	NS2
Botswana: BOT1101804A	S2

Manufacturer:

Novartis Pharma Produktions GmbH

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