NOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

MYFORTIC® 180 mg, 360 mg Film-Coated Tablets

Each film-coated tablet contains:

Myfortic 180 mg:
180 mg Mycophenolic acid (equivalent to 192.4 mg Mycophenolate sodium)

Myfortic 360 mg:
360 mg Mycophenolic acid (equivalent to 384.8 mg Mycophenolate sodium)

Inactive ingredients: see section 6 "Further Information" and section 2 "Important information regarding some of the ingredients of the medicine".

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

Important information for your review
- Warning: mycophenolate causes miscarriages and birth defects. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and follow the contraception advice given to you by the attending doctor.
- Your doctor will speak to you, particularly on the effects of mycophenolate on unborn babies. Please study the information thoroughly and follow the instructions.
- Before taking this preparation, consult the doctor again if you did not fully understand the instructions.
For further information, see "Special warnings regarding use of the medicine" section and "Pregnancy, breast-feeding and contraception" section.

1. WHAT IS THE MEDICINE INTENDED FOR?

Myfortic is given in combination with ciclosporin and corticosteroids to prevent graft rejection in adult kidney transplant patients.
If you have any questions about how Myfortic works or why this medicine has been prescribed for you, contact the doctor.

Therapeutic group: Immunosuppressants.

2. BEFORE USING THE MEDICINE

Myfortic will only be prescribed for you by a doctor with experience in transplantation medicines.

Do not use this medicine if:
- you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or any of the other ingredients contained in the medicine, listed in section 6 "Further Information" in this leaflet.
- you are a woman of child-bearing age and you have not provided a negative pregnancy test before your first prescription for Myfortic, as mycophenolate causes miscarriages and birth defects.
- you are pregnant, planning to become pregnant or think you may be pregnant.
- you are a woman of child-bearing age and do not use effective contraceptives (for further information, see "Pregnancy, breast-feeding and contraception" section).
- you are breast-feeding (for further information, see "Pregnancy, breast-feeding and contraception" section).

If any of the above apply to you, tell your attending doctor and do not take the medicine.

Special warnings regarding use of the medicine:

Before treatment with Myfortic, tell the doctor or pharmacist:
- if you have or have ever had a serious digestive problem, such as stomach ulcer.
- if you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome.

You should also be aware that:
- This medicine damages the defense mechanism of the skin from the sun. This increases the risk of skin cancer. You should limit your exposure to sunlight and ultraviolet (UV) light by covering exposed skin areas as much as possible and applying sunscreens with a high protection factor. Ask your doctor for advice on protection from the sun.
- If you already had viral hepatitis B or C, use of 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 or eyes, nausea, loss of appetite, dark urine), you should inform your doctor immediately.
- If you get a persistent cough or become breathless, especially when taking other immunosuppressants, you should tell your doctor straight away.
- Your doctor may check your blood level of antibodies during treatment with Myfortic particularly when the infections recur, especially if you are also taking other immunosuppressants, and will tell you whether you can continue taking Myfortic.
- If you get any symptoms of infection (such as fever, sore throat), unexpected bruising and/or bleeding, you should inform your doctor immediately.
- Your doctor may check your white blood cell count during treatment with Myfortic, and will tell you whether you can continue taking Myfortic.
- The active substance in the medicine, called "mycophenolic acid", is not the same as other similar-sounding medicines such as "mycophenolate mofetil". You should not switch between medicines unless your doctor tells you to.
- Use of Myfortic during pregnancy may harm the foetus (see also "Pregnancy, breast-feeding and contraception") and increase the risk of pregnancy loss (spontaneous abortion).
- In patients planning a pregnancy, alternative immunosuppressants, with a lower risk of toxicity to the unborn baby, should be considered. Discuss the risk versus benefit of treatment with the doctor.
- You must not donate blood during treatment with Myfortic and for at least 6 weeks after stopping treatment.
- Men must not donate semen during treatment with Myfortic and for at least 90 days after stopping treatment.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.
In particular, inform the doctor or pharmacist if you are taking:
- other immunosuppressant medicines such as: azathioprine or tacrolimus.
- medicines used to treat high blood cholesterol levels such as: cholestyramine.
- activated charcoal used to treat digestive problems such as diarrhoea, abdominal pain, and gas.
- antacids that contain magnesium and aluminium.
- medicines used to treat viral infections such as aciclovir or ganciclovir.

You should also tell your doctor if you plan to have any **vaccinations**.

Use of the medicine and food
Myfortic can be taken with or without food. You need to choose whether to take your tablets with or without food and then take them in the same way each day. This is to make sure that the same amount of your medication is absorbed into your body each day.

Elderly people
Elderly people (age 65 years or older) can take Myfortic without any need to adjust the dosage.

Children and adolescents
The use of Myfortic in children and adolescents is not recommended due to lack of data.

Pregnancy, breast-feeding and contraception
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the attending doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternative treatments you can take to prevent rejection of your transplanted organ if you:
- plan to become pregnant.
- missed or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- have sex without using an effective method of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking mycophenolate until the next meeting with the doctor.

Pregnancy
Mycophenolate causes a very high frequency of miscarriage (about 50%) and of 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 - the bones of the spine do not develop properly). Your baby may be affected by one or more of these defects.
If you are a woman of child-bearing age, do not start treatment with Myfortic before you provide a negative pregnancy test before starting treatment. Follow the contraception advice given to you by the attending doctor. Your doctor may request more than one pregnancy test to ensure you are not pregnant before starting treatment.

Breast-feeding
Do not take Myfortic if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Contraception in women taking Myfortic
If you are a woman of child-bearing age, you must use an effective method of contraception at the following time periods:
- Before you start taking Myfortic.
- During your entire treatment with Myfortic.
- For 6 weeks after you stop taking Myfortic.

Talk to the attending doctor about the most suitable contraception for you. These contraceptive measures will be determined by 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 are not capable of becoming pregnant if any of the following criteria applies to you:
- You are a woman of post-menopausal age, 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, diagnosed by a gynaecology specialist).
- 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 the female partners of men taking Myfortic
The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, the risk is not completely negligible.
As a precaution, it is recommended that you or your female partner use reliable contraception during treatment and for 90 days after you stop taking Myfortic.
If you are planning a pregnancy with your female partner, talk to your doctor about the potential risks.

Driving and using machines
It is unlikely that Myfortic will affect your ability to drive or use machines.

Important information regarding some of the ingredients of the medicine

Myfortic contains sodium
This medicine contains 13 mg of sodium (main component of cooking salt) in each Myfortic 180 mg tablet, which is equivalent to 0.65% of the maximum daily intake of sodium recommended for an adult by the World Health Organization (2 grams).

This medicine contains 26 mg of sodium (main component of cooking salt) in each Myfortic 360 mg tablet. This amount is equivalent to 1.3 % of the recommended maximum daily intake of sodium for an adult.

This preparation contains lactose (also see section 6 "Further Information").
If you have been told by a doctor that you have an intolerance to some sugars (including lactose, galactose, or glucose), contact your doctor before taking Myfortic.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage and dosing frequency
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.

Method of administration
Swallow the tablet whole with a glass of water.
Since the tablets are film-coated, do not chew, break or crush the tablets. Do not swallow a broken or split tablet.

Duration of Myfortic treatment
Treatment will continue for as long as you need immunosuppression in order to prevent rejection of your transplanted kidney.

If you accidentally took a higher dosage
If you took an overdose, or if a child or someone else has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of this medicine with you. Medical attention may be necessary. Take the tablets with you and show them to your doctor or to the hospital staff. If you have run out of tablets, take the empty packaging with you.

If you forget to take the medicine
If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, unless it is almost time for your next dose. Then continue taking the medicine at the usual times. Ask your doctor for advice.
Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine
Do not stop taking this medicine unless your doctor tells you to. Stopping your treatment with Myfortic may increase the risk of your transplanted kidney being rejected.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Myfortic may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Elderly patients may experience more side effects due to a weaker immune system.
Immunosuppressants, including Myfortic, reduce your body's own defense mechanisms to stop you from rejecting your transplanted organ. Consequently, your body will not be as good as normal at fighting infections. Therefore, if you are taking Myfortic, you may suffer from more infections than usual, including: infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract. The doctor will perform regular blood tests to monitor any changes in the number of your blood cells or in the levels of other substances carried in your blood, such as sugar, fat and cholesterol.

Some side effects may be serious:

Refer to a doctor immediately if:
- you have symptoms of infection including fever, chills, sweating, feeling tired, drowsy, or lack of energy. If you are taking Myfortic, you may be more likely to get viral, bacterial and fungal infections than usual. This may affect various body systems, the most common being the kidneys, bladder, and upper and/or lower airways.
- you are suffering from vomiting blood, black or bloody stools, stomach or intestinal ulcer.
- you have enlarged glands, new skin growths or enlargement of existing skin growths, or changes in an existing mole. As can happen in patients taking immunosuppressants, a very small number of Myfortic patients have developed cancer of the skin or lymph nodes.

Other side effects:

Very common side effects - effects that occur in more than 1 user in 10:
- low level of white blood cells.
- low level of calcium in the blood (hypocalcaemia).
- low level of potassium in the blood (hypokalaemia).
- high level of uric acid in the blood (hyperuricemia).
- high blood pressure (hypertension).
- anxiety.
- diarrhoea.
- pain in joints (arthralgia).

Common side effects - effects that occur in 1-10 in 100 users:
- low level of red blood cells which can result in tiredness, breathlessness and looking pale (anaemia).
- low level of blood platelets which can result in unexpected bleeding and bruising (thrombocytopenia).
- high level of potassium (hyperkalemia).
- low level of magnesium (hypomagnesemia).
- dizziness.
- headache.
- cough.
- low blood pressure (hypotension).
- shortness of breath.
- abdominal or stomach pain, inflammation of the lining of the stomach, abdominal bloating, constipation, indigestion, wind (flatulence), loose stools, nausea, vomiting.
- tiredness, fever.
- abnormal results of liver or kidney function tests.
- respiratory infection.
- acne.
- weakness (asthenia).
- muscle pain (myalgia).
- swollen hands, ankles or legs (possible symptoms of peripheral oedema).
- itching.

Uncommon side effects - effects that occur in 1-10 in 1,000 users:
- fast heart beat or irregular heart beat (ventricular extrasystoles), pulmonary oedema.
- cyst containing lymph fluid.
- trembling, difficulty in sleeping.
- redness and swelling of eyes (conjunctivitis), blurred vision.
- wheezing.
- belching, bad breath, bowel blockage, lip ulcers, heartburn, tongue discolouration, dry mouth, inflammation of the gums, inflammation of the pancreas leading to severe upper stomach pain (pancreatitis), blockage of the salivary glands, inflammation of the inner lining of the abdomen (peritonitis).
- infection of the bones, blood and the skin.
- blood in urine, damage to the kidney, pain and difficulty passing urine.
- hair loss, skin bruising.
- inflammation of the joints (arthritis), back pain, muscle cramps.
- loss of appetite, increased level of lipids (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or decreased level of phosphate in the blood.
- flu symptoms (such as: tiredness, chills, sore throat, aching joints or muscles), swelling of ankles and feet, pain, rigors, weakness or feeling thirsty.
- strange dreams, delusions.
- inability to get or keep an erection.
- cough, difficulty breathing, painful breathing (possible symptoms of interstitial lung disease).

Side effects of unknown frequency (frequency cannot be estimated from the available data):
- rash.
- fever, sore throat, frequent infections [possible symptoms of lack of white cells in the blood (agranulocytosis)].

Other side effects reported following use of medicines similar to Myfortic:
Additional side effects have been reported following use of medicines belonging to the same group that Myfortic belongs to: inflammation of the colon, inflammation of the stomach lining caused by a CMV virus (cytomegalovirus), development of a hole in the intestinal wall, resulting in severe abdominal pain with possible bleeding, stomach or duodenal ulcers, reduction in the number of specific white blood cells or of all blood cells, serious infections such as: inflammation of the heart and its valves, infection of the membrane that covers the brain and spinal cord, shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) and other less common bacterial infections that may develop into a serious lung disorder (tuberculosis and atypical mycobacterial infection).
Talk to your doctor if you develop a persistent cough or breathlessness.
If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless clearly indicated by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C. Protect from moisture.
- Keep in the original package.
- Do not use the medicine if you notice that the package is damaged or has signs of tampering.
- Do not throw away the medicine into the trash or the sink. Consult with the pharmacist on how to discard a medicine that you do not need. This will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Lactose anhydrous, crospovidone, povidone (K-30), maize starch, colloidal silicon dioxide, magnesium stearate.
Composition of the tablet coating:
Myfortic 180 mg -
Hypromellose phthalate, titanium dioxide (CI 77891, E-171), iron oxide yellow (CI 77492, E-172), indigotine
Myfortic 360 mg -
Hypromellose phthalate, titanium dioxide (CI 77891, E-171), iron oxide yellow (CI 77492, E-172), iron oxide red (CI 77491, E-172)
Each Myfortic 180 mg tablet contains 45 mg lactose (anhydrous) and 13 mg sodium.
Each Myfortic 360 mg tablet contains 90 mg lactose (anhydrous) and 26 mg sodium.
- What the medicine looks like and the contents of the package
Myfortic 180 mg: a lime green, film-coated, round tablet, with bevelled edges and the imprint "C" on one side of the tablet.
Myfortic 360 mg: a pale orange/red, film-coated, oblong tablet, with the imprint "CT" on one side of the tablet.
Package size: 120 tablets.
- Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.
- Revised in November 2021 according to MOH guidelines.
- Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Myfortic 180 mg: 128 30 30715
Myfortic 360 mg: 128 33 30716

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