NOVARTIS

Before prescribing, consult full prescribing information of Myfortic® (mycophenolate sodium).

(https://www.swissmedicinfo.ch/)

Information for patients

Read this leaflet carefully before taking/using this medicine.
This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours.
Keep this leaflet. You may want to read it again later.

MYFORTIC®

What MYFORTIC is and what it is used for
Myfortic is a gastro-resistant film-coated tablet, contains the active substance mycophenolic acid and belongs to a class of medicines called immunosuppressants. Immunosuppressants are used to reduce your body's immune response to materials that are foreign to the body, particularly a transplanted organ.
Myfortic aims to stop the body from rejecting a transplanted kidney in adult patients. Myfortic is used together with other medicines – ciclosporin and corticosteroids (cortisone).
Myfortic must only be taken if it has been prescribed by a doctor.

Do not take/use MYFORTIC
Myfortic can lead to severe birth defects in unborn children and miscarriages. Therefore, do not take Myfortic if you are pregnant, think you are pregnant or plan to become pregnant during treatment or within 6 weeks after treatment.
Do not take Myfortic if you are breast-feeding.
If you could become pregnant, talk to your doctor about the best methods of contraception.
If you could become pregnant but cannot or do not wish to use the necessary contraceptives, do not take Myfortic.
If you are allergic to mycophenolic acid, mycophenolate mofetil, lactose, galactose or any of the other ingredients of Myfortic.

Warnings and precautions
Myfortic can lead to severe birth defects in unborn children and miscarriages. Therefore, talk to your doctor about the best method of contraception.
If you have the rare metabolic disorders Lesch-Nyhan syndrome or Kelley-Seegmiller syndrome, you should not take Myfortic. Therefore, tell your doctor if you have either of these disorders.
Myfortic weakens your body's defence mechanisms. For this reason, there is an increased risk of skin cancer. You should therefore limit your exposure to sunlight and UV rays as much as possible by wearing special clothing that protects you from sunlight and regularly using a sunscreen with a high protection factor.
If you have already had hepatitis B or C, Myfortic may increase the risk of these diseases reappearing. Your doctor may perform blood tests and check you for signs of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine), you should inform your doctor immediately.
Due to the body's decreased defences, infections with pathogens may occur more frequently. Myfortic may also affect the formation of blood in the bone marrow. Therefore, if you experience any signs of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding, you should tell your doctor immediately.
This medicine may make COVID-19 more severe. In such cases your doctor will consider appropriate clinical measures.
During treatment with Myfortic vaccinations may be less effective. Vaccination with a live vaccine should be avoided. Your doctor will advise you on whether or not you can have a vaccination.
If you have or have had severe gastrointestinal problems such as a stomach ulcer, tell your doctor, as Myfortic should be used with particular caution in such cases.
Your doctor will perform regular blood tests to monitor any change in the number of blood cells and the concentration of various substances transported in the blood.
As Myfortic contains lactose, caution is required if you are allergic (hypersensitive) to lactose.

Interactions with other medicines
Myfortic should not be taken with medicines used to treat excess stomach acid (antacids containing magnesium and aluminium hydroxide) as this affects the absorption of Myfortic.
Colestyramine (used to reduce blood fats), certain antibiotics, the substances aciclovir and ganciclovir (used to treat viral diseases) and tacrolimus, another medicine used to suppress the immune system, may only be taken at the same time as Myfortic if you are closely monitored by a doctor.
Azathioprine, another medicine used to suppress the immune system, should not be taken with Myfortic.
The possibility that Myfortic may reduce the effectiveness of oral contraceptives cannot be ruled out.

Ability to use machines or drive
This medicine does not appear to affect the reactions, the ability to drive or the ability to use machines.
Please tell your doctor or pharmacist:
- If you have any other illnesses
- If you have allergies or
- If you are taking or externally applying any other medicines (including non-prescription medicines).

Please only take MYFORTIC after talking to your doctor if you have a known intolerance to sugar.
Myfortic 180 mg film-coated tablet: This medicine contains less than 1 mmol (23 mg) of sodium per film-coated tablet, making it practically "sodium-free".
Myfortic 360 mg film-coated tablet: This medicine contains 26 mg of sodium (the main component of salt) per film-coated tablet. This is equivalent to 1.3% of the recommended maximum daily dietary sodium intake for an adult.

Pregnancy and breast-feeding
Myfortic must not be used during pregnancy as it may harm your unborn child and increases the risk of miscarriage.
Before starting treatment with Myfortic, pregnancy must be ruled out. Therefore, there must be 2 negative pregnancy tests within 8-10 days, with the last of these possibly having to be performed immediately before the start of treatment. Additional pregnancy tests should be performed during follow-up appointments.
If you could become pregnant but cannot or do not wish to use the necessary contraceptives, do not take Myfortic. However, if you do become pregnant, contact your doctor immediately.
Women who may become pregnant must use 2 reliable methods of contraception before using, while using and for 6 weeks after using Myfortic.
If you are pregnant, think you are pregnant or plan to become pregnant, talk to your doctor about this.
If you are breast-feeding, talk to your doctor about this. Do not breast-feed while taking Myfortic.
Sexually active men (able to have children and vasectomised) are advised to use a condom during treatment and for at least 90 days after the last dose. In addition, female partners of male patients are advised to use a reliable method of contraception during treatment and for at least 90 days after the last dose.
Do not use Myfortic if you are breast-feeding.

How to use MYFORTIC
The recommended dose is 720 mg twice daily. This means that you should take four 180 mg film-coated tablets or two 360 mg film-coated tablets each morning and evening. The first dose should be taken within 48 hours after transplantation.
Take the film-coated tablets with a glass of water. Do not break or crush the film-coated tablets and do not take any film-coated tablets that are broken or otherwise damaged. You may take Myfortic with or without food.
You should continue use for as long as you require immunosuppressive treatment to prevent rejection of your transplanted kidney.
There is no experience of use in children or adolescents. Therefore, the use of Myfortic in children and adolescents cannot be recommended.

If you take more Myfortic than you should
If you take more film-coated tablets than you have been prescribed by your doctor or if someone else accidentally takes your medicine, you or the affected person should see a doctor or go to a hospital immediately.

If you forget to take Myfortic
If you forget to take a dose of Myfortic, take it when you realise and then continue to take Myfortic at the usual times. Ask your doctor for advice.

Possible effects of stopping treatment with Myfortic
Stopping treatment with Myfortic can increase the risk of rejection of your transplanted organ. Do not stop taking your medicine under any circumstances unless your doctor advises you to.
Do not change the prescribed dosage yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects
The following side effects may occur when taking Myfortic:

Very common (affecting more than 1 in 10 patients):
Diarrhoea; reduction in the number of white blood cells, infections (see below); reduced calcium concentration in the blood, sometimes leading to cramps (hypocalcaemia); muscle weakness, muscle cramps, irregular heart rhythm (possible signs of a low level of potassium in the blood (hypokalaemia)); abnormal blood test results (high uric acid level in the blood (hyperuricaemia)); headache, dizziness (possible signs of high blood pressure (hypertension)); dizziness, light-headedness (possible signs of low blood pressure (hypotension)).
In children of women who have taken a mycophenolic acid derivative such as Myfortic in combination with other immunosuppressive medicines during pregnancy, congenital deformities have been observed. Spontaneous miscarriages (mainly in the first trimester) have also occurred during pregnancy.

Common (affecting 1 to 10 in 100 patients):
More rapid occurrence of bleeding and bruising (signs of a decreased number of blood platelets), anaemia; muscle spasms, irregular heart rhythm (possible signs of a high level of potassium in the blood (hyperkalaemia)); abnormal blood test results (low level of magnesium in the blood (hypomagnesaemia)); excessive emotional stress, agitation (signs of anxiety); dizziness; headache; cough; headache, light-headedness, possibly with nausea (possible signs of severe high blood pressure (worsened hypertension)); shortness of breath, difficulty breathing (possible signs of dyspnoea or exertional dyspnoea); pain (e.g. in the abdomen, stomach); constipation; indigestion; flatulence; soft stools; inflammation of the stomach lining; nausea; vomiting; tiredness; fever; change in liver or kidney test results; joint pain (arthralgia), weakness (asthenia); muscle pain (myalgia).

Uncommon (affecting fewer than 1 in 100 patients):
Cysts containing lymph fluid; difficulty sleeping, trembling; heart palpitations; lung congestion; shortness of breath; belching; bad breath; bowel obstruction; pancreas or oesophagus inflammation; stomach or duodenal ulcer, gastrointestinal bleeding (bloody or black stools); dry mouth, lip lesions; salivary gland blockage, heartburn, gum inflammation, inflammation of the abdominal cavity; flu-like symptoms, chills; swelling of the hands, ankles and feet; loss of appetite; back pain; hair loss; bruising; acne; conjunctivitis (with eye discharge, itching, redness and swelling), blurred vision; delusion; kidney problems, narrowing of the tube through which urine passes, blood in urine; cough, breathing problems, pain when breathing (possible signs of interstitial lung disease, including fatal pulmonary fibrosis), skin rash; fever, sore throat, frequent infections (possible signs of a lack of white blood cells; agranulocytosis); change in blood sugar, increased blood cholesterol and fats; cancers (see below).

Frequency not known (cannot be estimated from the available data):
Fever, joint pain, joint swelling (de novo purine synthesis inhibitors-associated acute inflammatory syndrome).
If you take Myfortic, you will be more susceptible to infections than normal. Infections may be caused by bacteria, viruses or fungi and occur in various organs or body systems. Infections of the upper airways are common, but the urinary tract (burning when urinating and needing to urinate more often or more urgently) and the skin are most commonly affected.
The following symptoms may be signs of a brain infection (progressive multifocal leukoencephalopathy): visual disturbances (e.g. disturbances in your field of vision), motor disorders, memory loss, difficulty speaking or understanding others, muscle weakness. In such cases contact your doctor immediately.
As for all patients taking immunosuppressive medicines, skin cancer or cancer of the white blood cells has also occurred during Myfortic treatment. The latter may be indicated by inflammation of the lymph nodes. Skin cancer may be indicated by a change in skin that is increasing in size, has an unusual, shiny or sore/ulcer-like appearance and does not go away.
If you notice any of the above side effects or other side effects not described in this leaflet, tell your doctor or pharmacist. However, you should never stop taking this medicine without discussing this with your doctor.

Further information
Store in the original pack. Do not store above 30°C.
Do not use after the expiry date (= EXP) printed on the pack.
Keep out of the reach of children.
Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

What MYFORTIC contains
Maize starch; povidone (K-30); crospovidone; lactose; colloidal silicon dioxide; magnesium stearate.

The gastro resistant tablet coating of Myfortic 180 mg consists of hypromellose phthalate/ hydroxypropylmethylcellulose phthalate; titanum dioxide; iron oxide yellow; indigotin.

The gastro resistant tablet coating of Myfortic 360 mg consists of hypromellose phthalate/ hydroxypropylmethylcellulose phthalate; titanum dioxide; iron oxide yellow; iron oxide red.

Information might differ in some countries.

Availability/pack sizes
Myfortic may only be obtained in a pharmacy with a doctor's prescription.

Myfortic 180 mg: 120 gastro-resistant film-coated tablets.

Myfortic 360 mg: 120 gastro-resistant film-coated tablets.

Not all pack sizes may be marketed in your country.

Manufacturer
Novartis Pharma Produktions GmbH, Wehr, Germany for Novartis Pharma AG, Basle, Switzerland.

Batch Releaser
Lek d.d., PE PROIZVODNJA LENDAVA, Trimlini 2D, Lendava, 9220 Slovenia.

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in January 2023.

® = registered trademark

NOVARTIS PHARMA AG, BASEL, SWITZERLAND

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists