

MYFORTIC[®] GASTRO-RESISTANT TABLETS

Mycophenolic acid (180mg, 360mg)

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What Myfortic is used for

Myfortic gastro-resistant tablets belong to the class of drugs known as immunosuppressants.

Immunosuppressants reduce your body's response to anything that it sees as "foreign" – which includes transplant organs.

How Myfortic works

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, pharmacist, or healthcare provider.

Before you use Myfortic

Myfortic will only be prescribed for you by a doctor experienced in transplantation medicine. Follow your doctor's instructions carefully. They might differ from the general information contained in this leaflet.

- When you must not use it

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 end of this leaflet.
- 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 (see Contraception in women and men).
- if you are breast-feeding (see also "Pregnancy and breast-feeding").

If any of the above apply to you, tell your doctor without taking Myfortic.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ if:

- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You 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 you see him or her.

Pregnancy

Mycophenolate causes a very high frequency of miscarriage (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 (where the bones of the spine are not properly developed)). Your baby may be affected by one or more of these.

If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor. Your doctor may request more than one 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 who could become pregnant you must always use two effective methods of contraception with Myfortic. This includes:

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

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. 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 a woman who is not capable of becoming pregnant if any of the following applies to you:

- You are post-menopausal, 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, which has been confirmed by a specialist gynaecologist)
- 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 men taking Myfortic

You must always use condoms during treatment and for at least 90 days after you stop taking Myfortic

If you are planning to have a child, your doctor will talk to you about the risks and the alternative treatments you can take to prevent rejection of your transplant organ.

- Before you start to use it

Take special care with Myfortic

During exposure to sunlight.

- Myfortic reduces your body's defense mechanism, causing an increased risk of skin cancer. You should 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 a blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) inform your doctor immediately.
- If you experience any symptoms of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding 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 deficiency of the enzyme hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan syndrome (also known as Kelley-Seegmiller syndrome).
- Use of Myfortic in pregnancy may increase the risk of birth defects and/or pregnancy loss including spontaneous abortion (see Pregnancy and breast-feeding). If you are a female of child-bearing 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. If you are pregnant, think you may

be pregnant or plan to become pregnant, ask your doctor for advice.

- If you are breast-feeding (see Pregnancy and breast-feeding).

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

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Remember to mention those you have bought without a prescription from your doctor; this includes antacids (medicines used to treat indigestion and heartburn). It is particularly important to tell your doctor if you are taking any of the following medicines:

- Azathioprine, or any other immunosuppressants.
- Cholestyramine (a medicine used to treat high blood cholesterol levels).
- Aciclovir (a medicine used to treat herpes infection).
- Antacids that contain magnesium and aluminium
- Ganciclovir (a medicine used to treat cytomegalovirus (CMV) infection).
- Before administration of live attenuated vaccines.
- Oral contraceptives.

Taking Myfortic with food and drink

Myfortic can be taken with or without food.

Older people (65 years of age or above)

Myfortic can be given to people aged over 65 years. No dose adjustment is required.

Children and adolescents (below 18 years)

There is very limited experience with Myfortic in children.

How to use Myfortic

Follow your doctor's instruction carefully. Do not exceed the recommended dosage.

- How much to use

The recommended daily dose is 1,440 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.

- When and how to take Myfortic

Swallow the tablets whole with a glass of water.

Do not break or crush the tablets.

Do not take any tablets that are broken or split.

- How long to use Myfortic

Treatment will continue for as long as you need immunosuppression to prevent rejection of your transplanted kidney.

- If you forget to take Myfortic

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.

- If you take more Myfortic than you should (overdose)

If you have accidentally taken too many tablets, talk to your doctor straight away. You may require medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

If you stop taking Myfortic

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

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.

- Things to be careful of

Driving and using machines

Myfortic is not likely to affect your ability to drive or use machines.

Side effects

As with all medicines, patients treated with Myfortic may experience side effects, although not everybody gets them.

Some of the more frequent problems are constipation, diarrhea, nausea, infections, and a reduction in the number of white blood cells. 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 in your blood, e.g. sugar, fat, and cholesterol.

Some side effects could be serious:

- 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 generalized 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 signs and symptoms of a brain infection 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, respiratory tract and 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 anemia (decrease in red blood cells).

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Other side effects may include:

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: may affect more than 1 in 10 people

- Low level of white blood cells.
- Reduced level of calcium in the blood, sometimes leading to cramps, (hypocalcemia)
- Muscle weakness, muscle spasms, abnormal heart rhythm (possible symptoms of low level of a potassium in the blood) (hypokalemia)
- Abnormal blood test results (high level of uric acid in the blood) (hyperuricemia)
- Headache, dizziness (possible symptoms of high blood pressure) (hypertension)
- Diarrhea

Common: may affect up to 1 in every 10 people

- bleeding or bruising more easily than normal (signs of low level of blood platelets),
- Muscle spasms, abnormal heart rhythm (possible symptoms of high level of potassium in the blood) (hyperkalemia) Abnormal blood test results (low level of magnesium in the blood) (hypomagnesemia)
- Excessive emotional distress, troubled sleep (symptoms of anxiety)
- Dizziness
- Dizziness, light-headedness (possible symptoms of low blood pressure) (hypotension)
- headache,
- Headache, dizziness, possibly with nausea (possible symptoms of severe high blood pressure) (aggravated hypertension)
- cough,
- Shortness of breath, difficulty breathing (possible symptoms of dyspnea or dyspnea exertional)
- 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.
- Joint pain (arthralgia) Weakness (asthenia)
- Muscle pain (myalgia)
- Swollen hands, ankles or feet (possible symptoms of edema peripheral)

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)

Other side effects reported with medicines similar to Myfortic

Additional side effects have been reported with the class of drugs which Myfortic belongs to:

- inflammation of the colon or of the esophagus;
- 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, 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 usually resulting in a serious lung disorder (*tuberculosis and atypical mycobacterial infection*).
- 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 any of these affects you, tell your doctor.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Myfortic

- Storage

- Do not store Myfortic above 30°C.
- Store 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.
- Keep out of the reach and sight of children.

- Disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

Product Description

- What it looks like

Myfortic is supplied as gastro-resistant tablets.

- Myfortic 180 mg comes as a lime green, film-coated round tablet, with bevelled edges and the imprint (debossing) “C” on one side.
- Myfortic 360 mg comes as a pale orange/red, film-coated ovaloid tablet, with the imprint (debossing) “CT” on one side.

Each tablet of Myfortic 180 mg contains 180 mg of the active substance mycophenolic acid as mycophenolate sodium.

Each tablet of Myfortic 360 mg contains 360 mg of the active substance mycophenolic acid as mycophenolate sodium.

This information might differ in some countries.

- Ingredients

180 mg and 360 mg gastro-resistant tablets

- Active ingredients

- The active substance of Myfortic is mycophenolic acid (as mycophenolate sodium).

- Inactive ingredients

- The other ingredients of Myfortic 180 mg are: Tablet core: maize starch, povidone (K-30), crospovidone, lactose, colloidal silicon dioxide, magnesium

stearate. Tablet coating: hypromellose phthalate/hydroxypropylmethylcellu

lose phthalate, titanium dioxide, iron oxide yellow, indigotine.

- The other ingredients of Myfortic 360 mg are: Tablet core: maize starch, povidone (K-30), crospovidone, lactose, colloidal silicon dioxide, magnesium stearate. Tablet coating: hypromellose phthalate/hydroxypropylmethylcellu lose phthalate, titanium dioxide, iron oxide yellow, iron oxide red.

- MAL Number

Myfortic 180mg Gastro-Resistant Tablets: MAL20040811ARZ

Myfortic 360mg Gastro-Resistant tablets: MAL20040812ARZ

Manufacturer

Novartis Pharma Produktions GmbH
Oflinger Strasse 44, 79664 Wehr
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Product Registration Holder

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