

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Mycophenolic acid Inovamed 180 mg Mycophenolic acid Inovamed 360 mg Delayed-release tablets

Each delayed-release tablet contains:

Mycophenolic acid Inovamed 180 mg:
180 mg Mycophenolic acid (equivalent to 192.351 mg Mycophenolate sodium)

Mycophenolic acid Inovamed 360 mg:
360 mg Mycophenolic acid (equivalent to 384.701 mg Mycophenolate sodium)

For a list of inactive and allergenic ingredients in the preparation: see section 6 "Further information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the 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 to treat 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 is able to conceive, you must undergo a pregnancy test with a negative result before starting treatment and follow the contraception advice given to you by the attending doctor.
 - Your doctor will discuss with you, in particular, the effects of mycophenolate on unborn babies. Please study the information thoroughly and follow the instructions.
 - Before taking the preparation, consult a doctor again if you did not fully understand the instructions.
- For more information, see the section "Special warnings regarding use of the medicine" and the section "Pregnancy, breastfeeding and contraception".

1. WHAT IS THE MEDICINE INTENDED FOR?

Mycophenolic acid Inovamed is given in combination with cyclosporine and corticosteroids to prevent graft rejection in adult kidney transplant recipients.

If you have any questions about how Mycophenolic acid Inovamed works or why this medicine has been prescribed for you, ask the doctor.

Therapeutic group: Immunosuppressants.

2. BEFORE USING THE MEDICINE

Mycophenolic acid Inovamed will only be prescribed to you by a doctor with experience in transplant medications.

Do not use the medicine if:

- You are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or to any of the additional ingredients contained in the medicine, listed in section 6 "Further information" and in section 2 "Important information about some of the ingredients of the medicine" in this leaflet.
 - You are a woman of childbearing age and did not have a negative pregnancy test before receiving the first prescription for Mycophenolic acid Inovamed. This is because mycophenolate causes miscarriages and birth defects.
 - You are pregnant, planning a pregnancy or you think you are pregnant.
 - You are a woman of childbearing age and you are not using effective contraception (for more information, see section "Pregnancy, breastfeeding and contraception").
 - You are breastfeeding (for more information, see section "Pregnancy, breastfeeding and contraception").
- If any of the conditions listed above apply to you, tell your attending doctor and do not take the medicine.

Special warnings regarding use of the medicine:

Before treatment with Mycophenolic acid Inovamed, tell the doctor or pharmacist:

- If you have or have had in the past a serious gastrointestinal disorder such as a stomach ulcer.
- If you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome.

Pay attention to the following as well:

- This medicine damages the defense mechanism of the body's skin against the sun. Therefore, it increases the risk of getting skin cancer. Limit your exposure to the sun and UV rays by covering exposed skin as much as possible and applying sunscreens with a high protective factor. Ask the doctor for advice on protection from the sun.
- If you have previously suffered from viral hepatitis of type B or C, use of Mycophenolic acid Inovamed may increase the risk of these diseases reoccurring. Your doctor may perform blood tests and check for symptoms of these diseases. If you experience any symptom (yellow skin or eyes, nausea, loss of appetite, dark urine), inform your doctor immediately.
- If you have a persistent cough or feel short of breath, especially while taking other immunosuppressants, tell your doctor immediately.
- Your doctor may check the levels of antibodies in your blood during treatment with Mycophenolic acid Inovamed and instruct you whether to continue taking Mycophenolic acid Inovamed, especially when there are recurrent infections and you are also taking other immunosuppressants.
- If you experience symptoms of an infection (such as fever, sore throat), unexpected bruises and/or bleeding, inform the doctor immediately.
- Your doctor may check your white blood cell levels during treatment with Mycophenolic acid Inovamed and instruct you on whether to continue treatment with Mycophenolic acid Inovamed.
- The active substance in the medicine called "mycophenolic acid" is not the same as the substance in other medicines that sound similar, such as "mycophenolate mofetil". Do not switch between the medicines without the doctor's instructions.
- Using Mycophenolic acid Inovamed during pregnancy may harm the unborn baby (see also "Pregnancy, breastfeeding and contraception") and increases the risk of pregnancy loss (miscarriage).
- In patients planning a pregnancy, treatment with alternative immunosuppressants with lower risk for fetal toxicity should be considered. The risk of the treatment versus the benefit should be discussed with the doctor.
- You must not donate blood during treatment with Mycophenolic acid Inovamed and for at least 6 weeks after ending treatment.
- Men must not donate semen during treatment with Mycophenolic acid Inovamed and for at least 90 days after ending treatment.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor or pharmacist if you are taking:

- Other medicines that suppress the immune system such as: azathioprine or tacrolimus.
 - Medicines used to treat high cholesterol levels in the blood such as: cholestyramine.
 - Activated charcoal used to treat digestive problems such as diarrhea, abdominal pain and gas.
 - Antacids containing magnesium and aluminum.
 - Medicines used to treat viral infection such as: acyclovir or ganciclovir.
- You should also tell the doctor if you plan to get any **vaccinations**.

Use of the medicine and food

Mycophenolic acid Inovamed can be taken with or without food. You need to choose whether to take the tablets with food or without food and then take them in the same way each day. This is to ensure that the same amount of medicine is absorbed into your body each day.

Elderly

The elderly (aged 65 years and over) can use Mycophenolic acid Inovamed without any need to adjust the dosage.

Children and Adolescents

Use of Mycophenolic acid Inovamed in children and adolescents is not recommended due to lack of data.

Pregnancy, breastfeeding and contraception

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult the attending doctor or pharmacist before taking the medicine. The doctor will discuss with you the risks in the case of pregnancy and alternative treatments to prevent rejection of your transplanted organ if you are:

- Planning a pregnancy.
- Missed or think you have missed a period, you have unusual menstrual bleeding, or you suspect that you are pregnant.
- You have had sexual intercourse without using an effective contraceptive.

If you become pregnant during treatment with mycophenolate, inform the doctor immediately. However, continue taking mycophenolate until you see the doctor.

Pregnancy

Mycophenolate causes miscarriages at a very high frequency (about 50%) and severe congenital defects (23%-27%) in the fetus.

Congenital defects that have been reported include: defects in the ears, eyes, face (cleft lip/cleft palate), in the development of the fingers, the heart, the esophagus (the tube that connects the throat to the stomach), the kidneys and the 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 Mycophenolic acid Inovamed before you provide a negative pregnancy test before starting treatment. Follow the contraception advice given to you by the attending doctor. The doctor may request more than one pregnancy test to ensure that you are not pregnant before starting treatment.

Breastfeeding

Do not use Mycophenolic acid Inovamed if you are breastfeeding, as small amounts of the medicine may pass into breast milk.

Contraception in women taking Mycophenolic acid Inovamed

If you are a woman of childbearing age, you must use an effective method of birth control during these time periods:

- Before starting treatment with Mycophenolic acid Inovamed.
- During the entire treatment with Mycophenolic acid Inovamed.
- For 6 weeks after stopping treatment with Mycophenolic acid Inovamed.

Consult the attending doctor regarding the most suitable means for you to prevent pregnancy. These contraceptive measures will be determined according to your situation. Two methods of birth control are preferable since this will reduce the risk of unintended pregnancy.

Contact the doctor as soon as possible if you think that the contraceptive was ineffective or if you forgot to take a birth control pill.

You are not likely to get pregnant if any of the following criteria apply to you:

- You are a woman of post-menopausal age, i.e., you are at least 50 years old and you had your last period more than a year ago (if you stopped getting your periods due to cancer treatment, there is still a chance that you will get pregnant).
- You underwent surgery to remove the Fallopian tubes and both ovaries (bilateral salpingo-oophorectomy).
- You underwent surgery to remove the uterus (hysterectomy).
- Your ovaries are not functioning (premature ovarian failure, which has been diagnosed by a gynecologist specialist).
- You were born with one of the following rare conditions which do not allow pregnancy: XY genotype, Turner's syndrome or uterine agenesis.
- You are a female child or adolescent who has not yet started to get her period.

Prevention of pregnancy in the female partners of men taking Mycophenolic acid Inovamed

The available evidence does not indicate an increased risk of birth defects or miscarriage if the father takes mycophenolate, however the risk is not completely eliminated.

In order to exercise caution, it is recommended that you or your female partner use reliable contraception during treatment and for 90 days after finishing to take Mycophenolic acid Inovamed.

If you are planning a pregnancy with your female partner, talk to your doctor about the possible risks.

Driving and using machines

Mycophenolic acid Inovamed has little effect on the ability to drive or use machines.

Important information about some of the ingredients of the medicine

Mycophenolic acid Inovamed contains sodium

- This medicine contains 10.96-14.81 mg of sodium (main component of cooking salt) in each **Mycophenolic acid Inovamed 180 mg tablet**. This amount is equivalent to 0.55-0.74% of the maximum daily intake of sodium recommended for an adult diet.
- This medicine contains 21.93-29.62 mg of sodium (main component of cooking salt) in each **Mycophenolic acid Inovamed 360 mg tablet**. This amount is equivalent to 1.10-1.48% of the maximum daily intake of sodium recommended for an adult diet.

Mycophenolic acid Inovamed contains lactose

(see also section 6 "Further information")
This medicine contains lactose anhydrous which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose or if you are unable to digest certain sugars, consult the doctor before taking Mycophenolic acid Inovamed.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the 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 frequency of administration

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Method of administration

The tablet should be swallowed whole with a glass of water.

Since the tablets are delayed-release tablets, do not chew, break or crush the tablets. Do not swallow a broken or split tablet.

Duration of treatment with Mycophenolic acid Inovamed

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 accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Medical treatment may be necessary. Take the tablets with you and show them to the doctor or the medical staff at the hospital. If you run out of tablets, take the empty package with you.

If you forget to take the medicine

If you forgot 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. Continue to take the medicine at the usual times. Consult the doctor. 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 treatment with the medicine, unless your doctor tells you to do so. Stopping treatment with Mycophenolic acid Inovamed may increase the risk of rejection of your transplanted kidney.

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 further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Mycophenolic acid Inovamed 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 suffer from more side effects due to a weaker immune system.

Immunosuppressants, including Mycophenolic acid Inovamed, reduce your body's defense mechanisms, to prevent you from rejecting the transplanted organ. As a result, your body's ability to fight infections is not as good as usual. Therefore, if you take Mycophenolic acid Inovamed, 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 conduct regular blood tests to monitor changes in the number of blood cells or the levels of other substances in the blood such as sugar, fat and cholesterol.

Some side effects may be serious:

Consult a doctor immediately if:

- You have a rash, itching, hives, shortness of breath or breathing difficulties, wheezing or cough, light-headedness, dizziness, changes in level of consciousness, hypotension, with or without mild generalized itching, skin redness and swelling of the face/throat (symptoms of a severe allergic reaction).
- You have symptoms of infection including fever, chills, sweating, feeling tired, sleepiness, or lack of energy. If you are being treated with Mycophenolic acid Inovamed, you may be more susceptible than usual to viral, bacterial and fungal infections. This may affect different body systems, the most common being the kidneys, bladder and upper and/or lower respiratory tract.
- You suffer from bloody vomiting, black or bloody stools, a stomach or intestinal ulcer.
- You have enlarged glands, new skin growths or enlargement of existing growths, or a change in existing moles (beauty marks). As can happen in patients treated with immunosuppressants, a very small number of patients treated with Mycophenolic acid Inovamed developed cancer of the skin or lymph nodes.

Other side effects:

Very common side effects, effects that occur in more than one user out of ten:

- Low level of white blood cells.
- Low calcium level in the blood (hypocalcemia).
- Low level of potassium in the blood (hypokalemia).
- High level of uric acid in the blood (hyperuricemia).
- High blood pressure.
- Anxiety.
- Diarrhea.
- Pain in the joints (arthralgia).

Common side effects, effects that occur in 1-10 users out of 100:

- Low level of red blood cells that may cause tiredness, shortness of breath and paleness (anemia).
- Low level of blood platelets that may cause unexpected bleeding and bruising (thrombocytopenia).
- High level of potassium (hyperkalemia).
- Low level of magnesium (hypomagnesemia).
- Dizziness.
- Headache.
- Cough.
- Low blood pressure.
- Shortness of breath.
- Abdominal or stomach pain, inflammation of the stomach wall, abdominal swelling, constipation, indigestion, flatulence, loose stools, nausea, vomiting.
- Tiredness, fever.
- Abnormal liver or kidney function test results.
- Respiratory tract infection.
- Acne.
- Weakness (asthenia).
- Muscle pain (myalgia).
- Swelling in the hands, ankles or legs (possible symptoms of peripheral edema).
- Itching.

Uncommon side effects, effects that occur in 1-10 users out of 1,000:

- Fast heartbeat or an irregular heart rhythm (ventricular extrasystoles), lung congestion (edema)
- A cyst containing lymph fluid.
- Trembling, difficulty sleeping.
- Redness and swelling of the eyes (conjunctivitis), blurred vision.
- Wheezing-like breathing sounds.
- Belching, bad breath, bowel obstruction, lip sores, heartburn, tongue discoloration, dry mouth, gingivitis, inflammation of the pancreas causing severe upper abdominal pain (pancreatitis), blocked salivary glands, inflammation of the peritoneum (peritonitis).
- Bone, blood and skin infection.
- Bloody urine, kidney damage, pain and difficulty urinating.
- Hair loss, skin bruising.
- Inflammation of the joints (arthritis), back pain, muscle cramps.
- Loss of appetite, increased blood level of lipids (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or a low level of phosphate in the blood.
- Flu symptoms (such as: tiredness, chills, sore throat, joint or muscle pain), swelling in the ankles and feet, pain, shaking, weakness or feeling thirsty.
- Strange dreams, delusions.
- Inability to obtain or maintain an erection.
- Cough, difficulty breathing, pain upon breathing (possible symptoms of interstitial lung disease).

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Rash.
- Fever, sore throat, frequent infections [possible symptoms of lack of white blood cells (agranulocytosis)].

Additional side effects reported due to the use of medicines similar to Mycophenolic acid Inovamed:

Additional side effects have been reported due to the use of medicines belonging to the same group of medicines Mycophenolic acid Inovamed belongs to:
Inflammation of the large intestine, inflammation of the stomach lining as a result of CMV virus (cytomegalovirus), development of a perforation in the intestinal wall causing severe abdominal pain with possible bleeding, ulcers in the stomach or duodenum, a decrease in the number of certain white blood cells or of all blood cells, serious infections such as: infection of the heart and heart valves, infection of the membrane that covers the brain and spinal cord, shortness of breath, cough that can be caused by bronchiectasis (a condition in which the airways in the lungs are abnormally dilated) and other bacterial infections that are less common that may develop into a serious lung disorder (tuberculosis and atypical mycobacterial infections).

See the doctor if you develop a persistent cough or shortness of breath.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the 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 safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Protect against moisture.
- Keep in original package.
- Shelf life after first opening the bottle: use within 60 days, but no later than the expiration date of the preparation.
- 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 can or the sink. Consult the pharmacist on how to throw away 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:

Anhydrous lactose, hypromellose phthalate (HP-50), crospovidone, povidone K30, maize starch B, colloidal silicon dioxide, magnesium stearate, titanium dioxide, ferric oxide yellow.

Mycophenolic acid Inovamed 180 mg also contains:
FD & C Blue 2 AL lake

Mycophenolic acid Inovamed 360 mg also contains:
Ferric oxide red

What the medicine looks like and the contents of the package

Mycophenolic acid Inovamed 180 mg: Lime green, round shaped, beveled edged, coated tablets, debossed with "B180" on one side and plain on other.

Mycophenolic acid Inovamed 360 mg: Pale orange-red, oval shaped, biconvex, coated tablets, debossed with "B360" on one side and plain on other side.

Packaging type: The medicine is supplied in a plastic bottle containing 120 delayed-release tablets. The bottle is packaged in a carton. The bottle is closed with a child-resistant cap. To open the container, press on the lid and turn counter-clockwise.

License Holder and Importer: Inovamed Ltd., P.O.B. 62, Even Yehuda.

Manufacturer: Biocon Pharma Ltd., Electronics City, Bengaluru, India.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Mycophenolic acid Inovamed 180 mg: 173-70-37504

Mycophenolic acid Inovamed 360 mg: 173-71-37505