

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## **Mycophenolic Acid Ofek 180 mg**

## **Mycophenolic Acid Ofek 360 mg**

### **Delayed release tablets**

Each delayed release tablet contains:

Mycophenolic Acid Ofek 180 mg:  
180 mg mycophenolic acid (equivalent to 192.4 mg mycophenolate sodium)

Mycophenolic Acid Ofek 360 mg:  
360 mg mycophenolic acid (equivalent to 384.8 mg mycophenolate sodium)

Inactive ingredients and allergens in this medicine: see section 6 'Additional information' and section 2 under 'Important information about some of this medicine's ingredients'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

### **Important information for your review**

- Warning: Mycophenolate causes miscarriages and birth defects. If you are a woman who can become pregnant, you must undergo a pregnancy test, the result of which must be negative before starting treatment and follow the contraception guidelines provided to you by your doctor.
- Your doctor will talk with you, particularly about the effects of mycophenolate on fetuses. Please learn the information thoroughly and follow the instructions.
- Before taking the medicine, consult your doctor if you have not fully understood the instructions. For further information, see section 'Special warnings about using this medicine' and section 'Pregnancy, breastfeeding, and contraception'.

### **1. What is this medicine intended for?**

Mycophenolic Acid Ofek is administered in combination with cyclosporine and corticosteroids for prevention of acute transplant rejection in adult kidney transplant recipients.

If you have questions about how Mycophenolic Acid Ofek works or why this medicine has been prescribed for you, contact your doctor.

**Therapeutic group:** Immunosuppressants.

### **2. Before using this medicine**

Mycophenolic Acid Ofek will be prescribed to you only by a doctor experienced in medicines for transplantation.

#### **Do not use this medicine if:**

- You are sensitive (allergic) to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or to any of the other ingredients in this medicine, listed in section 6 'Additional information'.

- You are a woman of childbearing potential and you did not undergo a pregnancy test, the result of which was negative before receiving the first prescription for Mycophenolic Acid Ofek, since mycophenolate causes miscarriages and birth defects.
- You are pregnant, plan to become pregnant or think that you are pregnant.
- You are a woman of childbearing potential and you are not using an effective contraceptive. (For further information, see section 'Pregnancy, breastfeeding, and contraception'.)
- You are breastfeeding (For further information, see section 'Pregnancy, breastfeeding, and contraception'.)

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

**Special warnings about using this medicine:**

**Before treatment with Mycophenolic Acid Ofek, tell your doctor or pharmacist:**

- If you have or have previously had a serious gastrointestinal disorder, such as a gastric ulcer.
- If you have a rare inherited deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) enzyme, such as Lesch-Nyhan or Kelley-Seegmiller syndrome.

**You should also pay attention to the following:**

- This medicine impairs the mechanism of skin protection from sunlight. Therefore, it increases the risk of getting skin cancer. Limit your exposure to sunlight and UV rays by covering exposed skin as much as possible and applying sunscreens with a high sun protection factor. Consult your doctor regarding protection from sunlight.
- If you have previously had viral hepatitis B or C, using Mycophenolic Acid Ofek may increase the risk of relapse of these diseases. Your doctor may perform blood tests and check the symptoms of these diseases. If you experience any symptom (yellowish skin or eyes, nausea, loss of appetite, dark urine), notify your doctor immediately.
- If you have persistent cough or experience shortness of breath, especially while taking other immunosuppressants, tell your doctor immediately.
- Your doctor may examine the blood levels of antibodies during treatment with Mycophenolic Acid Ofek and instruct you if you should continue taking Mycophenolic Acid Ofek, especially if there are recurrent infections and you are taking other immunosuppressants as well.
- If you experience infection symptoms (such as fever, sore throat), unexpected bruising and/or bleeding, notify your doctor immediately.
- Your doctor may examine the levels of white blood cells during treatment with Mycophenolic Acid Ofek and instruct you if you should continue treatment with Mycophenolic Acid Ofek.
- The active substance of the medicine called 'mycophenolic acid' is not identical to the active substance of other medicines with similar-sounding names, such as 'mycophenolate mofetil'. Do not exchange the medicines without your doctor's instruction.
- Using Mycophenolic Acid Ofek during pregnancy may harm the fetus (see also 'Pregnancy, breastfeeding, and contraception') and increases the risk of pregnancy loss (a spontaneous miscarriage).
- In patients planning to become pregnant, alternative immunosuppressants with a lower risk of toxicity to the unborn baby should be considered. Discuss the risk versus benefit of the treatment with your doctor.
- Do not to donate blood during treatment with Mycophenolic Acid Ofek and for at least 6 weeks following treatment completion.
- Men should not donate semen during treatment with Mycophenolic Acid Ofek and for at least 90 days following treatment completion.

### **Interactions with other medicines**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

**Particularly inform your doctor or pharmacist if you are taking:**

- Other immunosuppressants such as azathioprine or tacrolimus.
- Medicines used for treatment of high blood cholesterol levels such as cholestyramine.
- Activated charcoal used for treatment of digestive problems such as diarrhea, abdominal pain and gas.
- Antacids containing magnesium and aluminum.
- Medicines used for treatment of viral infections such as acyclovir or ganciclovir.

You should also tell your doctor if you plan to receive any **vaccines**.

### **Using this medicine and food**

Mycophenolic Acid Ofek should be taken on an empty stomach, 1 hour before or 2 hours after food intake, to ensure that the same amount of medicine is absorbed in the body every day.

### **Elderly patients**

Elderly patients (aged 65 years and older) can use Mycophenolic Acid Ofek with no need for dosage adjustment.

### **Children and adolescents**

Use of Mycophenolic Acid Ofek in children and adolescents is not recommended due to lack of information about such use.

### **Pregnancy, breastfeeding, and contraception**

If you are pregnant or breastfeeding, think that you are pregnant or plan to become pregnant, consult your doctor or pharmacist before taking the medicine. Your doctor will talk with you about the risks in case of pregnancy and alternative treatments for prevention of transplant rejection if:

- You plan to become pregnant.
- You have missed or think that you have missed a menstrual period, experience abnormal menstrual bleeding, or suspect that you are pregnant.
- You have had a sexual intercourse without using an effective contraceptive.

If you become pregnant during treatment with Mycophenolic Acid Ofek, notify your doctor immediately. However, continue taking Mycophenolic Acid Ofek until the next appointment with your doctor.

### Pregnancy

Mycophenolate causes a very high incidence of miscarriages (about 50%) and severe fetal congenital malformations (23%-27%).

Reported congenital malformations include malformations of the ears, eyes, face (cleft lip/cleft palate), abnormalities in the development of fingers/toes, heart, esophagus (the tube connecting the throat to the stomach), kidneys and nervous system (for example spina bifida – the spinal bones are not developing properly). The baby may be harmed by one or more of these malformations.

If you are a woman of childbearing potential, do not start treatment with Mycophenolic Acid Ofek without a negative pregnancy test before treatment initiation. Follow the contraception guidelines provided to you by your doctor. Your doctor may request more than one pregnancy test to ensure that you are not pregnant before treatment initiation.

### Breastfeeding

Do not use Mycophenolic Acid Ofek if you are breastfeeding, since small quantities of the medicine may pass into breast milk.

### Contraception in women taking Mycophenolic Acid Ofek

If you are a woman of childbearing potential, you must use an effective contraception method during the following periods:

- Before starting treatment with Mycophenolic Acid Ofek.
- Throughout the entire treatment with Mycophenolic Acid Ofek.
- For 6 weeks after discontinuing treatment with Mycophenolic Acid Ofek.

Consult your doctor regarding the contraceptives that are most appropriate for you. These contraceptives will be determined in accordance with your condition. Two contraception methods are preferable, since this will reduce the risk of unintended pregnancy.

**Contact your doctor as soon as possible if you think that the contraceptive was not effective or if you forgot to take a contraceptive pill.**

If you meet any of the following criteria, you are not supposed to become pregnant:

- You are a menopausal woman. That is, you are at least 50 years old and you had your last menstrual period more than one year ago (If your menstrual period stopped due to cancer treatment, there is still a chance that you may become pregnant).
- You underwent surgical removal of fallopian tubes and both ovaries (bilateral salpingo-oophorectomy).
- You underwent surgical removal of the uterus (hysterectomy).
- The ovaries are dysfunctional (premature ovarian failure diagnosed by a gynecologist).
- You were born with one of the following rare conditions, which do not enable you to become pregnant:  
XY genotype, Turner's syndrome or lack of uterus development (uterine agenesis).
- You are a girl or an adolescent before menarche.

### Contraception in female partners of men taking Mycophenolic Acid Ofek

The existing evidence does not indicate increased risk of birth defects or miscarriages if the father is taking mycophenolate, however the risk cannot be completely excluded.

To exercise caution, you or your partner are advised to use a reliable contraceptive during the treatment and for 90 days after completing Mycophenolic Acid Ofek intake. If you and your partner are planning a pregnancy, talk with your doctor regarding the possible risks.

### **Driving and using machines**

Mycophenolic Acid Ofek has little effect on the ability to drive or use machines.

### **Important information about some of this medicine's ingredients**

#### **Mycophenolic Acid Ofek contains sodium**

This medicine contains 12 mg sodium (the main component of table salt) in each tablet of Mycophenolic Acid Ofek 180 mg. This quantity is equivalent to 0.65% of the maximum recommended daily dietary intake of sodium for adults.

This medicine contains 25 mg sodium (the main component of table salt) in each tablet of Mycophenolic Acid Ofek 360 mg. This quantity is equivalent to 1.3% of the maximum recommended daily dietary intake of sodium for adults.

#### **Mycophenolic Acid Ofek contains lactose**

If you have been told by your doctor that you have an intolerance to certain sugars (such as lactose, galactose or glucose), contact your doctor before taking Mycophenolic Acid Ofek.

### **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

#### **Dosage and administration frequency**

Only your doctor will determine your dose and how you should take this medicine.

**Do not exceed the recommended dose.**

#### **Manner of administration**

Swallow the tablet whole with a glass of water.

Since the tablets are coated, you must not chew, break or crush the tablets.

Do not swallow a broken or split tablet.

#### **Duration of treatment with Mycophenolic Acid Ofek**

The treatment will continue as long as you need immunosuppression to prevent rejection of the transplanted kidney.

#### **If you have accidentally taken a higher dose**

If you have taken an overdose, or if a child or anyone else has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Medical treatment may be required.

#### **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 the time of the next dose intake is close. Continue taking the medicine at regular times. Consult your doctor.

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

Adhere to the treatment as recommended by your doctor.

#### **If you stop taking this medicine**

Do not stop treatment with the medicine, unless instructed to do so by your doctor. Stopping treatment with Mycophenolic Acid Ofek may increase the risk of rejection of the transplanted kidney.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### **4. Side effects**

As with any medicine, using Mycophenolic Acid Ofek may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Elderly patients may have more side effects because of a weaker immune system.

Immunosuppressants, including Mycophenolic Acid Ofek, reduce the body's defense mechanisms to prevent you from rejecting the transplanted organ. As a result, the body's ability to fight infections is less good than normal. Therefore, if you are taking Mycophenolic Acid Ofek, you may suffer from infections more than usual, including infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract.

Your doctor will conduct regular blood tests to monitor changes in the number of blood cells or in the levels of other substances in the blood, such as sugar, fat and cholesterol.

**Certain side effects may be severe:**

**Contact your doctor immediately if:**

- You have symptoms of infection including fever, chills, sweating, sensation of tiredness, sleepiness or lack of energy. If you are treated with Mycophenolic Acid Ofek, you may be susceptible to viral, bacterial and fungal infections more than usual. This may affect various body systems, among which the most commonly affected are the kidneys, urinary bladder and upper and/or lower respiratory tract.
- You suffer from bloody vomit, black or bloody stool, gastric or intestinal ulcer.
- You have enlarged lymph nodes, new skin tumors or enlargement of existing skin tumors, or a change in existing moles. As may occur in patients treated with immunosuppressants, a very small number of patients treated with Mycophenolic Acid Ofek developed skin or lymph node cancer.

**Other side effects:**

**Very common side effects** - affect more than one in ten users:

- Low level of white blood cells
- Low blood calcium level (hypocalcemia)
- Low blood potassium level (hypokalemia)
- High blood uric acid level (hyperuricemia)
- High blood pressure
- Anxiety
- Diarrhea
- Joint pain (arthralgia)

**Common side effects** - affect 1–10 in 100 users:

- Low level of red blood cells, which may cause tiredness, shortness of breath and pallor (anemia)
- Low level of platelets, which may cause unexpected bleeding and bruising (thrombocytopenia)
- High potassium level (hyperkalemia)
- Low magnesium level (hypomagnesemia)
- Dizziness
- Headache
- Cough
- Low blood pressure
- Shortness of breath
- Abdominal or stomach pain, gastric wall inflammation, abdominal bloating, constipation, dyspepsia, wind (flatulence), soft stool, nausea, vomiting
- Tiredness, fever
- Abnormal results of liver or kidney function tests
- Respiratory tract infection
- Acne
- Weakness (asthenia)
- Muscle pain (myalgia)
- Swelling of hands, ankles or legs (possible symptoms of peripheral edema)
- Itching

**Uncommon side effects** - affect 1–10 in 1,000 users:

- Rapid heartbeat or irregular heart rate (ventricular extrasystoles), pulmonary congestion (edema)
- A cyst containing lymph fluid
- Tremor, difficulty sleeping
- Eye redness and swelling (conjunctivitis), blurred vision
- Wheezing breath sounds
- Belching, bad breath, intestinal obstruction, lip sores, heartburn, tongue discoloration, dry mouth, gum inflammation, pancreas inflammation causing severe pain in the upper abdomen (pancreatitis), salivary gland obstruction, inflammation of the peritoneum (peritonitis)
- Bone, blood and skin infection
- Bloody urine, damage to the kidneys, pain and difficulty in urination
- Hair loss, skin bruises
- Joint inflammation (arthritis), back pain, muscle cramps
- Loss of appetite, increased blood level of fats (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or low blood phosphate (phosphorus) level
- Flu symptoms (e.g. tiredness, chills, sore throat, joint or muscle pain), swelling of ankles and feet, pain, tremor, weakness or feeling thirsty
- Bizarre dreams, delusions
- Inability to achieve or maintain erection
- Cough, difficulty breathing, pain upon breathing (possible symptoms of interstitial lung disease)

**Side effects of unknown frequency** (the frequency cannot be estimated from the available information):

- Rash
- Fever, sore throat, frequent infections (possible symptoms of white blood cell deficiency [agranulocytosis])

**Additional side effects reported due to use of medicines similar to Mycophenolic Acid Ofek:**

Additional side effects have been reported due to use of medicines belonging to the same group of medicines as Mycophenolic Acid Ofek: colitis, gastric wall inflammation resulting from CMV (cytomegalovirus) infection, development of intestinal wall perforation causing severe abdominal pain with possible bleeding, gastric or duodenal ulcers, decreased number of certain white blood cells or of all blood cells, severe infections such as infectious endocarditis (infection of the heart and heart valves), meningitis (infection of the membranes surrounding the brain and spinal cord), shortness of breath, cough that may be caused by bronchiectasis (a condition in which the lung airways become abnormally widened) and other less common bacterial infections, which may develop into a severe pulmonary disorder (tuberculosis and atypical mycobacterial infections).

Contact your doctor if you develop a persistent cough or shortness of breath.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

## 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Protect from moisture.
- After opening the bottle, the tablets can be used for 2 months.
- 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 waste bin or sink. Ask the pharmacist how to dispose of medicines you no longer need. This will help protect the environment.

## 6. Additional information

- **In addition to the active ingredient, this medicine also contains:**

Lactose anhydrous, croscopovidone, povidone, pregelatinized starch, magnesium stearate.

Tablet coating composition:

Mycophenolic Acid Ofek 180 mg -

Hypromellose phthalate, triethyl citrate, hypromellose type 2910, Opadry II white (31K58901), Opacode WB black (NS-78-17821)

Mycophenolic Acid Ofek 360 mg -

Hypromellose phthalate, triethyl citrate, hypromellose type 2910, Opadry complete film coating system 03F63022 orange, Opacode WB black (NS-78-17821).

- **What the medicine looks like and contents of the pack**

Mycophenolic Acid Ofek 180 mg: white film-coated round tablets.

Mycophenolic Acid Ofek 360 mg: orange film-coated oval tablets.

Pack size: A plastic bottle containing 120 tablets. A package with child-resistant closure.

- **Registration holder's name and address:** Ofek Pharma Ltd., 22 Snir St., Bnei Dror 4581500.

- **Manufacturer's name and address:**

Twi Pharmaceuticals, Inc., 4f, No. 41, Lane 221, Kang Chien Rd., Taipei 11494, Taiwan

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

Mycophenolic Acid Ofek 180 mg: 173-68-37462-99

Mycophenolic Acid Ofek 360 mg: 173-69-37463-99