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

The medicine is dispensed with a doctor's prescription only

Mycophenolate Teva 500 mg

Tablets

Composition:

Each tablet contains:

Mycophenolate mofetil 500 mg

For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 - "Further Information".

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 for the treatment of your ailment only. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Important information for your review

- Warning: Mycophenolate causes miscarriages and birth defects. Do not commence treatment with Mycophenolate Teva in women of child-bearing age, without a negative pregnancy test before starting the treatment.
- Follow the instructions for contraception that will be given to you by the attending doctor.
  If you did not fully understand the instructions, consult the doctor again before taking the medicine.
  For further information, see section "Special warnings regarding use of the medicine" and section "Pregnancy, contraception and breastfeeding".

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine Mycophenolate Teva is used, in combination with cyclosporin and corticosteroids, to prevent rejection of a transplanted organ in kidney, heart or liver transplant patients.

Therapeutic group

Immunosuppressants.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are allergic to mycophenolate mofetil, to mycophenolic acid, or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients, see section 6 – "Further information").
- You are a woman of child-bearing age and you have not undergone a negative pregnancy test before receiving the first prescription of Mycophenolate Teva, as mycophenolate causes miscarriages and birth defects.
- You are pregnant, planning a pregnancy or think you are pregnant.
- You are a woman of child-bearing age and you do not use effective contraceptive methods (for further information, see "Pregnancy, contraception and breastfeeding" section).
- You are breastfeeding.

If any of the above-mentioned conditions apply to you, do not take the medicine.

If you are not sure, refer to your attending doctor or pharmacist before taking Mycophenolate Teva.

Special warnings regarding use of the medicine

Do not begin treatment with Mycophenolate Teva and refer to the attending doctor immediately if:

- you are older than the age of 65, as you may have an increased risk of developing side effects, such as: certain viral infections, gastrointestinal bleeding, and pulmonary edema when compared to younger patients.
- you have a sign of an infection, such as: a fever or sore throat.
- you have unexpected bruising or bleeding.
- you have, or have had in the past, problems with the digestive system (such as: a stomach ulcer).
- you are planning to become pregnant or if you become pregnant during the course of treatment with the medicine.
- you have a hereditary enzyme deficiency such as Lesch-Nyhan and Kelley-Seegmiller syndrome.

If any of the above-mentioned conditions apply to you (or if you are not sure), refer to the attending doctor immediately, before taking the medicine.

The effect of sunlight on the treatment

Mycophenolate Teva reduces your body's defense mechanisms. As a result, there is an increased risk of developing skin cancer. Limit your exposure to the sun and to UV radiation by:

- Wearing protective clothing that also covers your head, neck, arms and legs.
- Using sunscreens with a high protection factor.

Children

Do not give this medicine to children younger than 2 years of age because based on the existing safety and efficacy information, no dose recommendations can be made for this age group.

Mycophenolate Teva and other medicines

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

It is important to do so, since Mycophenolate Teva may affect the way other medicines work, and other medicines may affect the way Mycophenolate Teva works. In particular, inform the doctor or pharmacist before commencing treatment with Mycophenolate Teva if you are taking the following medicines:

- Azathioprine or other immunosuppressants given after a transplantation.
- Cholestyramine – a medicine to treat high cholesterol.
- Rifampicin – an antibiotic intended to prevent and treat infections such as tuberculosis (TB).
- Antacids, or proton pump inhibitors (PPIs) – preparations to treat problems of gastric hyperacidity, such as indigestion.
- Phosphate binders – given to patients with chronic kidney failure, to reduce the amount of phosphate absorbed into the blood.
- Antibiotics – used to treat bacterial infections.
- Isavuconazole – used to treat fungal infections.
- Telmisartan – used to treat high blood pressure.

Vaccines

If you are supposed to receive a vaccination (a live-attenuated vaccine) while being treated with Mycophenolate Teva, first refer to your doctor or pharmacist. The attending doctor will advise you on which vaccines you can receive.

Blood donation

Do not donate blood during treatment with Mycophenolate Teva and for at least 6 weeks after completing the treatment.

Sperm donation

Do not donate sperm during treatment with mycophenolate and for at least 90 days after completing the treatment.

Use of the medicine and food

Food and drink have no effect on treatment with Mycophenolate Teva.

Pregnancy, contraception and breastfeeding

Contraception in women taking Mycophenolate Teva

Women of child-bearing age who have been prescribed Mycophenolate Teva, must use an effective method of contraception:

- before starting treatment with Mycophenolate Teva.
- during the entire course of treatment with Mycophenolate Teva.
- for 6 weeks after discontinuation of treatment with Mycophenolate Teva.

Consult the attending doctor about the most suitable contraceptive methods for you. These contraceptives will be determined in accordance with your condition. It is preferable to use two forms of contraception as this will reduce the risk of an unplanned pregnancy.

Refer to the doctor as soon as possible, if you think your contraception was not effective or if you have forgotten to take a contraceptive pill.

If you meet any of the following criteria, you are not capable of becoming pregnant:

- You are a post-menopausal woman, i.e., you are at least 50 years old and you got your last menstrual period more than a year ago (if you stopped getting your period due to treatment for cancer, there is still a chance that you can become 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 do not function (premature ovarian failure, which has been diagnosed by a specialist gynecologist).
- You were born with one of the following rare conditions that make getting pregnant impossible: the XY genotype, Turner syndrome or lack of development of the uterus (Uterine agenesis).
- You are a girl or adolescent girl who has not yet started having periods.

Contraception in men taking Mycophenolate Teva

- The available data do not indicate an increased risk of malformations or miscarriage if the father is taking mycophenolate. However, the possibility of a risk can not be completely ruled out. As a precaution, you or your female partner are advised to use reliable contraception during treatment and for 90 days after completing the treatment.
- If you are planning a pregnancy with your female partner, talk with the doctor about the potential risks and alternative therapies.

Pregnancy and breastfeeding

Consult the attending doctor or pharmacist before taking the medicine if you are pregnant, breastfeeding, planning a pregnancy or think you are pregnant.

The doctor will discuss with you the risks in pregnancy and the alternative treatments you can take to prevent rejection of the transplanted organ, in the following cases:

- You are planning a pregnancy.
- You miss or think you have missed a period, you have unusual menstrual bleeding, or you suspect you are pregnant.
- You had sex without using an effective contraceptive methods.

If you become pregnant during the course of treatment with Mycophenolate Teva, inform the doctor immediately. However, keep taking Mycophenolate Teva until your meeting with the doctor.

Pregnancy

Mycophenolate causes a very high frequency of miscarriages (50%) and severe birth defects (23%-27%).

Birth defects which have been reported include: anomalies of ears, eyes, face (cleft lip/palate), development of fingers, heart, esophagus (the 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 the defects listed above.

Do not commence treatment with Mycophenolate Teva in women of child-bearing age without a negative pregnancy test before starting the treatment. Follow the contraceptive guidelines which will be given to you by the attending doctor. The doctor may request an additional pregnancy test to ensure that you are not pregnant before starting treatment.

Breastfeeding

Do not use Mycophenolate Teva if you are breastfeeding, since small amounts of the medicine may penetrate into the breast milk.

Driving and operating machinery

Mycophenolate Teva has a moderate effect on the ability to drive or use tools and machinery. If you feel drowsy, numb or confused, talk to the doctor or nurse and do not drive or use tools or machinery until you feel better. Children should be cautioned against riding a bicycle or playing near a road, and the like.

Important information about some of the ingredients of the medicine

The medicine contains the following ingredients:

- Allura Red #40 (FD&C Red #40 / Allura Red AC Aluminium lake (E129)), which may cause allergic reactions.
- Sodium: The sodium content in this medicine is less than 23 mg per tablet, thus, the medicine is considered essentially sodium free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

Recommended dosage

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

The dosage depends on the type of transplantation you have had. The recommended dosages are provided below.

The treatment will continue as long as it is necessary to prevent your body from rejecting the transplanted organ.

Do not exceed the recommended dosage.

Kidney transplant

Adults:

- The first dose is given within 3 days of the transplantation.
- The daily dosage is 2 grams Mycophenolate Teva, divided into two separate doses: 1 gram in the morning and 1 gram in the evening.

Children (aged 2 to 18 years):

- The dosage depends on the size of the child.
- The attending doctor will determine the most appropriate dosage, according to the height and weight of your child.

Heart transplant

Adults:

- The first dose is given within 5 days of the transplantation.
- The daily dosage is 3 grams Mycophenolate Teva, divided into two separate doses: 1.5 grams in the morning and 1.5 grams in the evening.

Children:

- There is no information regarding administration of Mycophenolate Teva to children after a heart transplant.

Liver transplant

Adults:

- The first dose of Mycophenolate Teva will be given to you at least 4 days after the transplantation and when you are able to swallow medicines.
- The daily dosage is 3 grams of Mycophenolate Teva, divided into two separate doses: 1.5 grams in the morning and 1.5 grams in the evening.

Children:

- There is no information regarding administration of Mycophenolate Teva to children after a liver transplant.

How to use the medicine

Swallow the tablets whole with a glass of water. Do not chew, break or crush the tablets. Do not halve the tablets.

Avoid contact between the powder and the skin, eyes and mouth. If the tablet accidentally broke, wash the powder residue from the skin with water and soap. If the powder penetrated the eyes/mouth, wash thoroughly with lots of water.

If you have accidentally taken a higher dosage, or if a child, or anyone else, has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember and continue taking the medicine at the designated times. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Do not stop treatment with Mycophenolate Teva, unless instructed to do so by your doctor. If you stop treatment, you may increase the risk of rejection of the transplanted organ.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

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 Mycophenolate Teva 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.

Refer to the doctor immediately if you notice any of the following severe side effects - you may need urgent medical treatment:

- You have a sign of an infection, such as a fever or sore throat.
- You are suffering from unexpected bruising or bleeding.
- You are suffering from a rash, swelling of the face, lips, tongue or throat, with difficulty in breathing – you may be having an acute allergic reaction to the medicine (such as anaphylactic shock, angioedema).

Common side effects

Some of the more common side effects are: diarrhea, fewer white or red blood cells in the blood, infection and vomiting. The attending doctor will perform regular blood tests to identify changes in:

- the number of your blood cells or signs of infections.

Children may be more likely than adults to suffer from the following side effects: diarrhea, infections, fewer white blood cells and red blood cells.

Protection from infections

The medicine Mycophenolate Teva reduces your body's defense mechanisms to prevent you from rejecting the transplanted organ. As a result, the ability of your body to fight infections is not as good as it normally is. Therefore, you may catch more infections than usual, including: infections of the brain, skin, mouth, stomach, intestine, lungs and urinary system.

Skin and lymph cancer

As may occur with patients taking medicines of this type (immunosuppressants), a very small number of patients who took Mycophenolate Teva developed cancer of the lymphoid tissues and skin.

Additional side effects

You may suffer from generalized side effects that affect the entire body, including: serious allergic reactions (such as: anaphylactic shock, angioedema), fever, feeling very tired, sleeping difficulties, pains (such as: abdominal pain, chest pain, joint or muscle pain), headache, flu symptoms and swelling.

Other side effects may include:

Skin problems, such as: acne, cold sores, shingles, skin growths, hair loss, rash and itching.

Urinary system problems, such as: blood in the urine.

Digestive system and mouth problems, such as:

- swelling of the gums and mouth ulcers.
- inflammation of the pancreas, colon or stomach.
- gastrointestinal disorders including bleeding.
- liver disorders.
- diarrhea, constipation, nausea, indigestion, loss of appetite, flatulence (gas in the digestive system).

Nervous system problems, such as:

- dizziness, sleepiness or numbness.
- tremor, muscle spasms, convulsions.
- feeling anxious or depressed, changes in mood or thoughts.

Heart problems and problems with the circulatory system, such as:

- changes in blood pressure, accelerated heart rate, widening of the blood vessels.

Lung problems, such as:

- pneumonia, bronchitis.
- shortness of breath, cough that can be caused as a result of bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lungs). Consult the doctor if you develop a persistent cough or breathlessness.
- fluid in the lungs or inside the chest.
- sinus problems.

Additional problems, such as: weight loss, gout, high blood sugar level, bleeding and bruising.

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 immediately.

Reporting side effects

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 should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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.

Storage conditions: Store in the original package, in a dry and dark place, below 25ºC.

Do not discard the medicine in the wastewater or household waste bin. Consult the pharmacist how to dispose of medicines no longer required. Taking these measures will help you protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Croscarmellose sodium, Povidone, Magnesium stearate.

HPMC 2910, Titanium dioxide, Macrogol/PEG 400, Talc, FD&C Red #40/Allura Red AC Aluminium lake (E129), FD&C Blue #2/Indigo carmine Aluminium lake.

What the medicine looks like and the contents of the package:

Each package contains purple, oval-shaped, coated tablets, with the number 93 debossed on one side of the tablet and the number 7477 debossed on the other side.

Each package contains 10, 30, 50 or 60 tablets in a blister pack (tray).

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020, Israel.

This leaflet was revised in April 2022 according to MOH guidelines.

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

142.37.32978