


CellCept PL version 10

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

This medicine is dispensed with a doctor’s prescription only

CellCept® 250 mg Capsules	CellCept® 500 mg Tablets	
Composition:	Each capsule contains:	Each film-coated tablet contains:
Mycophenolate mofetil 250 mg	Mycophenolate mofetil 250 mg	Mycophenolate mofetil 500 mg

*For information on the inactive ingredients and allergens, see section 2 “Before using the medicine” and section 6 “Further Information”.

•**Read this 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 illness only. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

IMPORTANT INFORMATION FOR YOUR REVIEW

Warning:

Mycophenolate causes miscarriages and birth defects. Do not begin treatment with **CellCept** in women of child-bearing age, who do not have a negative pregnancy test before starting treatment.

Follow the contraception instructions given to you by the attending doctor. Before taking the preparation, consult the doctor again if you did not fully understand the instructions. For further information, see section “Special warnings regarding use of this medicine” and “Pregnancy, contraception and breast-feeding” section.

1. WHAT IS THE MEDICINE INTENDED FOR?

CellCept is used, in combination with cyclosporine and corticosteroids, to prevent rejection of a transplanted organ in kidney, heart or liver transplant recipients.

Therapeutic group

Immunosuppressants.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are allergic to mycophenolate mofetil, mycophenolic acid, or to any of the other 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 provided a negative pregnancy test before receiving your first prescription of **CellCept**, as mycophenolate causes miscarriages and birth defects.
- You are pregnant, planning to become pregnant 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 section “Pregnancy, contraception and breast-feeding”).
- You are breast-feeding.

If any of the above conditions applies to you, do not take the medicine. If you are not sure, refer to your attending doctor or pharmacist before taking **CellCept**.

Special warnings regarding use of this medicine
Do not start treatment with CellCept and refer to the attending doctor immediately if:

- you are older than 65 years as you may have an increased risk of developing adverse events such as certain viral infections, gastrointestinal bleeding, and pulmonary oedema 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 are suffering, or have suffered in the past, from problems with the digestive system (such as: a stomach ulcer)
- you are planning to become pregnant or if you become pregnant during treatment with the medicine
- you have a hereditary enzyme deficiency such as **Lesch-Nyhan** and **Kelley-Seegmiller** syndrome.

If any of the above conditions applies 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

CellCept reduces your body’s defense mechanisms. As a result, there is an increased risk of developing skin cancer. Limit your exposure to sunlight and to UV radiation by:

- Wearing protective clothing, which 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 because based on the existing safety and efficacy information no dose recommendations can be made for this age group.

CellCept 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, as **CellCept** may affect the way some other medicines work, and other medicines can affect the way **CellCept** works. In particular, tell the doctor or pharmacist if you are taking any of the following medicines before you start treatment with **CellCept**:

- Azathioprine or other medicines which suppress the immune system and are given after a transplant operation.
- Cholestyramine - a medicine used to treat high cholesterol.
- Rifampicin - an antibiotic intended to prevent and treat infections such as tuberculosis (TB).
- Antacids, or proton pump inhibitors (PPIs) – preparations used to treat problems with excessive acidity in your stomach such as indigestion.
- Phosphate binders - given to patients with chronic kidney failure, to reduce the amount of phosphate that is absorbed into the blood.
- Antibiotics - used to treat bacterial infections.
- Isavuconazole - used to treat fungal infections.
- Telmisartan - used to treat high blood pressure.

Vaccinations

If you need to have a vaccine (a live-attenuated vaccine) while taking **CellCept**, first refer to your doctor or pharmacist. The attending doctor will have to advise you on what vaccines you can have.

You must not donate blood during treatment with **CellCept** and for at least 6 weeks after stopping treatment.

You must not donate semen during treatment with **CellCept** and for at least 90 days after stopping treatment.

Use of the medicine and food

Food and drink have no effect on your treatment with **CellCept**.

Pregnancy, contraception and breast-feeding

Contraception in women taking CellCept:

Women of child-bearing age who were prescribed **CellCept**, must use an effective method of contraception:

- Before starting treatment with **CellCept**
- During the entire treatment with **CellCept**
- For 6 weeks after stopping treatment with **CellCept**

Consult the attending doctor about the most suitable methods of contraception for you. These contraception methods will be determined depending on your condition. Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy.

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 cannot become pregnant if any of the following conditions applies to you:

- You are post-menopausal, i.e. you are 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, there is still a chance you could become pregnant)
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy)
- Your 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 syndrome or lack of development of the uterus (Uterine agenesis)
- You are a child or teenager who has not started having periods

Contraception in men taking CellCept

•The available data do not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, a risk cannot be completely excluded. As a precaution, you or your female partner are advised to use reliable contraception during treatment and for 90 days after you stop taking **CellCept**.

- If you are planning a pregnancy with your partner, talk to your doctor about the potential risks and alternative therapies.

Pregnancy and breast-feeding

If you are pregnant, breast-feeding, planning a pregnancy or think you are pregnant, consult the attending doctor or pharmacist before taking the preparation.

The doctor will talk to you about the risks of pregnancy and the alternative treatments which can be taken to prevent rejection of your transplant organ in the following cases:

- 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 had sex without using effective methods of contraception Inform your doctor immediately if you become pregnant during the treatment with **CellCept**. However, keep taking **CellCept** until you meet with the doctor.

Pregnancy

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

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

Do not begin treatment with **CellCept** in women of child-bearing age, without providing a negative pregnancy test before starting treatment. Follow the contraception instructions given to you by the attending doctor. The doctor may request an additional pregnancy test to ensure you are not pregnant before starting treatment.

Breast-feeding

Do not take **CellCept** if you are breast-feeding, since small amounts of the medicine can pass into the mother’s milk.

Driving and using machines

CellCept has a moderate effect on your ability to drive and use tools and machines. If you feel drowsy, numb, or confused talk to your doctor or nurse and do not drive or use tools and machines until you feel better.

CellCept contains sodium

This medicine contains less than 1 millimole of sodium (23 mg) per capsule/tablet so it is considered ‘sodium free’.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor’s instructions.

Check with the doctor or pharmacist if you are not sure.

Usual dosage

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

The dosage depends on the type of transplant you have had. The usual dosages are listed below.

The treatment will continue for as long as there is a need to prevent your body from rejecting your transplant organ.

Do not exceed the recommended dose.

Kidney transplant

Adults:

- The first dose is given within 3 days of the transplant operation.
- The daily dosage is 2 g of **CellCept**, divided into two separate doses: 1 g in the morning and 1 g 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 based on your child’s height and weight.

Heart transplant

Adults:

- The first dose is given within 5 days of the transplant operation.
- The daily dosage is 3 g of **CellCept**, divided into two separate

doses: 1.5 g in the morning and 1.5 g in the evening.

Children:

- There is no information regarding use of **CellCept** in children after a heart transplant.

Liver transplant

Adults:

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

Children:

- There is no information regarding use of **CellCept** in children after a liver transplant.

Instructions for use of the medicine

Swallow the capsules/tablets whole with a glass of water.

Do not break or crush the capsules/tablets.

Capsules: Do not open or split the capsules. Do not take capsules that have been opened or split.

Avoid contact between powder that has spilled out of damaged capsules and the skin, eyes and mouth. If a capsule has been accidentally opened/broken, wash the residue of the powder from the skin with water and soap. If powder gets into your eyes/mouth, wash thoroughly with a lot of water.

If you accidentally took 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 to take the medicine at the usual times. Do not take a double dose to make up for a missed dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Do not stop treatment with **CellCept**, unless your doctor has instructed you to do so. If you stop your 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 the doctor.

If you have any further questions regarding use of this medicine, ask the doctor or pharmacist.

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

4. SIDE EFFECTS

As with any medicine, use of **CellCept** may cause side effects in some users. Do not be alarmed by 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 suffer from unexpected bruising or bleeding
- you suffer from a rash, swelling of the face, lips, tongue or throat, with difficulty in breathing - you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema).

Common side effects

Some of the more common side effects are: diarrhoea, fewer white cells or red 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: diarrhoea, infections, fewer white cells and fewer red cells in the blood.

Protection from infections

CellCept reduces your body’s defence mechanisms, to prevent you from rejecting the transplanted organ. As a result, your body’s ability to fight infections will not be as good as it normally is. Therefore, you may catch more infections than usual, including: infections of the brain, skin, mouth, stomach, gut, lungs and urinary system.

Lymph and skin cancer

As can happen in patients taking these types of medicines (immune-suppressants), a very small number of patients who took **CellCept** 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: anaphylaxis, angioedema), fever, extreme fatigue, difficulty sleeping, pains (such as: abdominal pain, chest pain, joint or muscle pain), headache, flu symptoms and swelling.

Other side effects can 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
 - diarrhoea, constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence (gas in the digestive tract)

Nervous system problems, such as:

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

Heart and blood system problems, such as:

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

Lung problems, such as:

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

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

If a side effect occurs, if one of the side effects mentioned above worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor immediately.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting side effects following 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 below 25°C, in a cool and dry place. Store in the original package to protect from moisture.
- The medicine should not be disposed of via wastewater or household waste. 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: Capsules 250 mg:

Capsules: starch pregelatinized, croscarmellose sodium, polyvidone K90, magnesium stearate.

Capsule shells:

Body:

titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), gelatin, printing ink.

Cap:

titanium dioxide (E171), indigo carmine FD&C blue 2 (E132), gelatin, printing ink.

Tablets 500 mg:

Tablets: microcrystalline cellulose, croscarmellose sodium, polyvidone K90, magnesium stearate.

Tablet Coating: hypromellose, hydroxypropyl cellulose, titanium dioxide (E171), macrogol 400, indigo carmine aluminium lake (E132), iron oxide red (E172).

What does the medicine look like and what are the contents of the package?

CellCept capsules are elongated capsules, one side is blue-colored and the other side is brown-colored. “CellCept 250” is imprinted in black on the blue side of the capsule, and “Roche” is imprinted in black on the brown side. The capsules are available in packages of 100 (in blister packs of 10).

CellCept tablets are elongated (caplet-shaped), film-coated lavender colored tablets. “CellCept 500” is imprinted on one side of the tablet and “Roche” is imprinted on the other side. The tablets are available in packages of 50 (in blister packs of 10).

License holder and address: Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.

Manufacturer and address: F. Hoffmann-La Roche Ltd., Basel, Switzerland.

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

CellCept 250 mg capsules: 111.34.29434

CellCept 500 mg tablets: 111.35.29435