

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### CELLCEPT

250 mg, capsule, hard

MYCOPHENOLATE MOFETIL

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

---

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

---

#### What is in this leaflet?

1. What CELLCEPT is and what it is used for
2. Before you take CELLCEPT
3. How to take use CELLCEPT
4. Possible side effects
5. How to store CELLCEPT
6. Further information

#### 1. WHAT CELLCEPT IS AND WHAT IT IS USED FOR

CellCept contains mycophenolate mofetil. This belongs to a group of medicines called “immunosuppressants”. CellCept is used to prevent your body rejecting a transplanted organ, such as kidney, heart or liver. CellCept should be used together with other medicines: Ciclosporin and corticosteroids.

#### 2. BEFORE YOU TAKE CELLCEPT

##### **Do not take CELLCEPT**

- If you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in this medicine (listed in Section 6)
- If you are breast-feeding
- If you are pregnant or planning to become pregnant or think you may be pregnant

If you are not sure, talk to your doctor or pharmacist before taking CELLCEPT.

##### **Take special care with CELLCEPT**

### **Warnings and precautions**

Talk to your doctor straight away before taking CellCept:

- If you have a sign of infection such as a fever or sore throat
- If you have any unexpected bruising or bleeding
- If you have ever had a problem with your digestive system such as a stomach ulcer
- If you are planning to become pregnant or if you get pregnant while taking CellCept

If any of the above apply to you (or you are not sure), talk to your doctor straight away before taking CellCept. CellCept reduces your body's defenses. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:

- wearing protective clothing which also covers your head, neck, arms and legs
- using a sunscreen with a high protection factor.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription including herbal medicines. This is because CellCept can affect the way some other medicines work. Also other medicines can affect the way CellCept works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start CellCept:

- azathioprine or other medicines which suppress your immune system – given after a transplant operation
- cholestyramine – used to treat high cholesterol
- rifampicin – an antibiotic used to prevent and treat infections such as tuberculosis (TB)
- antacids or proton pump inhibitors – used for acid problems in your stomach such as indigestion
- phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood.
- If you need to have a vaccine (a live vaccine) while taking CellCept, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

### **Taking CELLCEPT together with food and drink**

Taking food and drink has no effect on your treatment with CellCept.

### **Pregnancy and breastfeeding**

Use of CellCept during pregnancy can lead to miscarriage or harm your unborn child (eg, problems with development of the ears).

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 do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking CellCept until you see him or her.

### **Do not take CellCept if you:**

- Breastfeed baby
- are pregnant (unless you do your doctor clearly tells you)

### **Tell your doctor immediately if you:**

- Think you may be pregnant
- Are breast-feeding a baby
- are planning to start a family in the near future

***You must always use an effective method of contraception:***

- Before you start taking CellCept
- Throughout the duration of treatment with CellCept
- During 6 weeks after the treatment with CellCept

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. 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.

**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 gynecologist)
- 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.

***Driving and using machines***

CELLCEPT is not likely to affect your ability to drive or use any tools or machines.

***3. HOW TO TAKE CELLCEPT***

Always take CELLCEPT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

***Kidney transplant***

**Adults**

- The first dose is given within 3 days of the transplant operation.
- The daily dose is 8 capsules (2 g of the medicine) taken as 2 separate doses.
- Take 4 capsules in the morning and then 4 capsules in the evening.

**Children (aged 2 to 18 years)**

- The dose given will vary depending on the size of the child.
- Your doctor will decide the most appropriate dose based on your child's height and weight (body surface area – measured as square meters or "m<sup>2</sup>"). The recommended dose is 600 mg/ m<sup>2</sup> taken twice a day.

***Heart transplant***

**Adults**

- The first dose is given within 5 days of the transplant operation.
- The daily dose is 12 capsules (3 g of the medicine) taken as 2 separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

**Children**

- There is no information for the use of CellCept in children with a heart transplant.

***Liver transplant***

**Adults**

- The first dose of oral CellCept will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medicines.

- The daily dose is 12 capsules (3 g of the medicine) taken as 2 separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

#### **Children**

- There is no information for the use of CellCept in children with a liver transplant.

#### ***Taking the medicine***

Swallow your capsules whole with a glass of water

- Do not break or crush them
- Do not take any capsules that have broken open or split.

#### ***If you take more CELLCEPT than you should***

If you take more CELLCEPT than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Also do this if someone else accidentally takes your medicine. Take the medicine pack with you.

#### ***If you forget to take CELLCEPT***

If you forget to take a dose, take it as soon as you remember it. Do not take a double dose to make up for a forgotten dose.

#### ***If you stop taking CELLCEPT***

Do not stop taking CellCept unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your transplant organ.

Talk to your doctor or pharmacist if you have any additional questions.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding
- you have a rash, swelling of your face, lips, tongue or throat, with difficulty breathing - you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema).

#### ***Usual problems***

Some of the more usual problems are diarrhea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

- the number of your blood cells
- the amount in your blood of things like sugar, fat or cholesterol.

Children may be more likely than adults to have some side effects. These include diarrhea, infections, fewer white cells and fewer red cells in the blood.

#### ***Fighting infections***

CellCept reduces your body's defenses. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

#### ***Lymph and skin cancer***

As can happen in patients taking this type of medicine (immune-suppressants), a very small number of CellCept patients have developed cancer of the lymphoid tissues and skin.

General unwanted effects

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle, pain on passing urine), headache, flu symptoms and swelling.

***Other unwanted effects may include:***

Skin problems such as:

- acne, cold sores, shingles, skin growth, hair loss, rash, itching.

**Urinary problems such as:**

- kidney problems or the urgent need to pass water (urine).

**Digestive system and mouth problems such as:**

- swelling of the gums and mouth ulcers,
- inflammation of the pancreas, colon or stomach,
- gut problems including bleeding, liver problems,
- constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence.

**Nervous system problems such as:**

- feeling dizzy, drowsy or numb,
- tremor, muscle spasms, convulsions,
- feeling anxious or depressed, changes in your mood or thoughts.

**Heart and blood vessel problems such as:**

- change in blood pressure, unusual heartbeat, 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 lung). Talk to your doctor if you develop a persistent cough or breathlessness
- fluid on the lungs or inside the chest,
- sinus problems.

**Other problems such as:**

- weight loss, gout, high blood sugar, bleeding, bruising.

***Reporting of side effects***

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

***5. HOW TO STORE CELLCEPT***

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

**Shelf life:** 3 years.

***Storage conditions:***

Do not store above 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What CELLCEPT contains**

- The active substance is mycophenolate mofetil.
- The other ingredients are:
- CellCept capsules: pregelatinised maize starch, croscarmellose sodium, polyvidone (K-90), magnesium stearate
- Capsule shell: gelatin, indigo carmine (E132), yellow iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), black iron oxide (E172), potassium hydroxide, shellac.

### **What CELLCEPT looks like and contents of the pack**

CellCept capsules are oblong shaped with one end blue and the other end brown. They have “CellCept 250” printed in black on the capsule cap and “company’s sign” printed on the capsule body.

1 box of CellCept contains 100 or 300 capsules (in blister packs of 10).

### **Regime of dispensing**

The medicine is issued on prescription.

### **Manufacturer**

F. Hoffmann - La Roche Ltd.,  
Basel, Switzerland