

CELLCEPT®

Mycophenolate Mofetil (Capsule 250 mg, Tablet 500 mg)

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What CELLCEPT is used for

CELLCEPT is used to prevent your body from rejecting a transplanted organ (kidney, heart or liver) and it should be used together with other medicines known as cyclosporine and corticosteroids.

CELLCEPT is used for treatment of kidney inflammation; lupus nephritis and it should be used together with other medicine known as corticosteroids.

Ask your doctor if you have any questions about why CELLCEPT has been prescribed for you. Your doctor may have prescribed CELLCEPT for another reason.

This medicine is available only with a doctor's prescription.

How CELLCEPT works

CELLCEPT contains mycophenolate mofetil. This belongs to a group of medicines called "immunosuppressants".

Immunosuppressants are used to prevent the rejection of a transplanted organ and work by stopping your immune system from reacting to the transplanted organ.

Before you use CELLCEPT

- When you must not use it

Do not take CELLCEPT if:

1. ***You have had an allergy or serious reaction (like anaphylaxis) to mycophenolate mofetil, mycophenolic acid, or any of the other ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:***
 - shortness of breath
 - wheezing or difficulty

breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives on the skin

2. You are pregnant

Mycophenolate causes a very high frequency of miscarriage and of severe birth defects in the unborn baby. Birth defects that have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, of esophagus (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 these.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately.

3. You are breastfeeding

Do not breastfeed while taking CELLCEPT. Small amounts of the medicine may pass into your breast milk and could cause serious side effects for your baby.

4. You are a woman who could become pregnant

Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy.

You must use an effective method of contraception with CELLCEPT. This includes: before you start taking CELLCEPT, during your entire treatment with CELLCEPT, and for 6 months after you stop taking CELLCEPT.

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.

5. The package is torn or shows signs of tampering

6. The expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

Talk to your doctor straight away before starting treatment with CELLCEPT 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.

If you are not sure if you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if:

1. You are pregnant or plan to become pregnant

- If you are a woman of child-bearing potential, you must provide a negative pregnancy test before starting treatment.
- Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

2. You are breast-feeding or plan to breast-feed

3. You are a sexually active man

- You are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy.
- Your female partner is recommended to use reliable contraception during treatment and for 90 days after you stop taking CELLCEPT.
- You must not donate semen during treatment with CELLCEPT and for at least 90 days stopping treatment.

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

5. You have any other health problems, especially the following:

- A history of problem(s) with your digestive system such as a stomach ulcer
- Kidney problem(s)
- Have a hereditary enzyme deficiency such as Lesch-Nyhan or Kelley-Seegmiller Syndrome

If any of the above apply to you (or you are not sure), talk to your doctor

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straight away before starting treatment with CELLCEPT.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, such as herbal medicines.

This is because CELLCEPT can affect the way some other medicines work. Also, other medicines can affect the way CELLCEPT works. These include:

- azathioprine, tacrolimus and sirolimus, medicines used to suppress the immune system which can be used to prevent organ rejection after a transplant
- acyclovir, ganciclovir, valacyclovir or valganciclovir, medicines used to treat viral infections
- isavuconazole, a medicine used to treat fungal infections
- cholestyramine, a medicine used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin, medicines used to treat infections
- certain vaccines (especially live vaccines), medicines that work by causing your body to produce its own protection against an infectious disease
- proton-pump inhibitors (such as lansoprazole and pantoprazole), medicines used to treat indigestion and stomach ulcers
- calcium-free phosphate binders (such as sevelamer), medicines used to treat high phosphate levels in the blood
- antacids, medicines used to treat heartburn and indigestion
- telmisartan, medicine used to lower blood pressure
- probenecid, medicine used to treat gout

How to use CELLCEPT

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Take CELLCEPT exactly as your doctor has prescribed.

Your doctor will tell you how many CELLCEPT capsules or tablets to take each day.

The dose to prevent organ rejection is usually 1 g to 1.5 g in the morning and 1 g to 1.5 g at night (2 g to 3 g per day) depending on which organ has been transplanted.

The dose to treat lupus nephritis is usually 1 g in the morning and 1 g at night (2 g per day).

Your doctor may adjust your dose depending on your response.

Taking the medicine

- Swallow the capsules or tablets whole with a glass of water.
- Do not break or crush them.
- Take care not to let any powder from inside a broken capsule get into your eyes or mouth. If this happens, rinse with plenty of plain water.
- Take care not to let any powder from inside a broken capsule get onto your skin. If this happens, wash the area thoroughly with soap and water.

- When to use it

It is best to take doses of CELLCEPT capsules or tablets approximately 12 hours apart.

Take your medicine at about the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

- How long to use it

CELLCEPT should be taken every day. It is important to keep taking CELLCEPT to ensure your new transplant keeps working properly.

Continue taking CELLCEPT for as long as your doctor tells you.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait till then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using CELLCEPT

- Things you must do

Tell all the doctors, dentists, and pharmacists treating you that you are using CELLCEPT.

Tell your doctor immediately if you become pregnant while using this medication.

Your doctor will do regular blood tests to check for any changes in the number of your blood cells or signs of infection.

The effect of sunlight

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 that covers your head, neck, arms and legs
- Using a sunscreen with a high protection factor

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

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not give CELLCEPT to anyone else, even if they have the same condition as you.

Do not use any new medicines without consulting your doctor or pharmacist.

- Things to be careful of

CELLCEPT has a moderate influence on your ability to drive or use any tools or machines.

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If you feel drowsy, numb or confused, talk to your doctor or nurse and do not drive or use any tools or machines until you feel better.

Side effects

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

Some of the more usual problems are diarrhea, fewer white cells or red cells in your blood, infection and vomiting.

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), headache, flu symptoms and swelling.

Other unwanted effects may include:

- Acne, cold sores, shingles, skin growth hair loss, rash, itching
- Blood in the urine
- Swelling of the gums and mouth ulcers
- Inflammation of the pancreas, colon or stomach
- Gastrointestinal disorders including bleeding
- Liver disorders
- Diarrhea, constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence
- Feeling dizzy, drowsy or numb
- Tremor, muscle spasms, convulsions
- Feeling anxious or depressed, changes in your mood or thoughts
- Change in blood pressure, accelerated heartbeat, widening of blood vessels
- 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).
- Fluid on the lungs or inside the chest
- Sinus problems
- Weight loss, gout, high blood sugar, bleeding, bruising

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 fevers 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). These reactions can happen very quickly, sometimes within minutes to a day after starting CELLCEPT. If this occurs, you will need immediate medical treatment and will likely need to stop taking CELLCEPT, or as advised by your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following: fever, joint pain and muscle pain.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of CELLCEPT

- Storage

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Keep CELLCEPT capsules in a cool dry place where the temperature stays below 25°C.

Keep CELLCEPT tablets in a cool dry place where the temperature stays below 30°C.

Keep out of the reach and sight of children.

- Disposal

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.

Product Description

CELLCEPT 250 mg capsules come in packs of 100 capsules.
CELLCEPT 500 mg tablets come in packs of 50 tablets.

- What it looks like

CELLCEPT capsules are oblong, blue on one end and brown on the other, printed with black ink "CELLCEPT 250" on the cap and "Roche" on the body.

CELLCEPT tablets are lavender colored and capsule shaped, engraved with "CELLCEPT 500" on one side and "Roche" on the reverse.

- Ingredients

Active ingredients:

- CELLCEPT capsules contain 250 mg of mycophenolate mofetil.
- CELLCEPT tablet contain 500 mg of mycophenolate mofetil.

Inactive ingredients:

CELLCEPT Capsule fill contains:

- Pregelatinised maize starch
- Croscarmellose sodium
- Povidone
- Magnesium stearate

CELLCEPT Tablet contains:

- Microcrystalline cellulose
 - Croscarmellose sodium
 - Povidone
 - Magnesium stearate
 - Opadry Lavender Y-5R- 10272-A
- CELLCEPT Tablets are gluten and lactose free.

- MAL number(s)

CELLCEPT Capsule 250 mg:
MAL06030803ACRZ
CELLCEPT Tablet 500 mg:
MAL06030804ACRZ

Manufacturer

Made for

F. Hoffmann-La Roche Ltd, Basel, Switzerland

by

Delpharm Milano S.r.l, Segrate, Italy

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Product Registration Holder

Roche (M) Sdn. Bhd.
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47500 Subang Jaya,
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