

CELLCEPT®

Mycophenolate Mofetil (250mg, 500mg)

What is in this leaflet

1. What Cellcept is used for
2. How Cellcept works
3. Before you take Cellcept
4. How to take Cellcept
5. While you are using Cellcept
6. Side effects
7. Storage and disposal of Cellcept
8. Product Description
9. Manufacturer & product registration holder
10. Date of revision

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 ciclosporin 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.

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

Cellcept is not addictive.

How Cellcept works

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

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

Immunosuppressants weaken the body's immune system so it will not produce auto-antibodies. The immune system of lupus patients produces auto-antibodies at a rapid rate, which in turn attack the immune system.

Before you take Cellcept

When you must not take it

Do not take Cellcept if:

1. **You have had an allergic reaction to Cellcept or any 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.**
Cellcept is harmful to an unborn baby when taken by a pregnant woman.
There have been cases of miscarriage and severe birth defects reported when patients took Cellcept during pregnancy. You must tell your doctor if you are pregnant or plan to become pregnant.
3. **You are breastfeeding.**
Cellcept may pass into human breast milk and could cause serious side effects in your baby if you breastfeed.
4. **You are a woman who could become pregnant and you are not using two reliable forms of contraception**
You must use two reliable forms of contraception at the same time before beginning Cellcept therapy, during therapy and for at least six weeks after stopping Cellcept, unless you are not sexually active
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.

If you are not sure if you should be taking Cellcept, talk to your doctor.

Before you start to take 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 have two negative pregnancy tests 8-10 days apart just prior to starting treatment with Cellcept.
Repeat pregnancy tests will be performed during routine follow-up visits with your doctor.
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 with Cellcept and for 90 days after stopping treatment, even if you have had a vasectomy.
Your female partner(s) are recommended to use reliable contraception while you are being treated with Cellcept and for 90 days after you have stopped receiving Cellcept.
4. **You have any other health problems, especially the following:**
 - a history of sun spots or skin cancers.
 - a history of low blood counts of neutrophils (a type of white blood cell).
 - a history of serious stomach or bowel problems (such as ulcers or bleeding).
 - kidney disease.
 - Rare hereditary deficiency of certain enzymes, such as Lesch-Nyhan Syndrome and Kelly-Seegmiller Syndrome.
5. **You are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, tell them before you start taking Cellcept.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought without a

CELLCEPT®

Mycophenolate Mofetil (250mg, 500mg)

prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Cellcept. These medicines include:

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

These medicines may be affected by Cellcept, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Cellcept.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take Cellcept

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Take Cellcept exactly as your doctor has prescribed.

Your doctor will tell you how many Cellcept capsules and 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).

How to take it

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

Do not crush Cellcept tablets and do not open or crush Cellcept capsules.

Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in Cellcept capsules. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.

When to take it

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

How long to take Cellcept

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

Continue taking Cellcept until your doctor tells you to stop.

If you forget to take Cellcept

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not double a dose to make up for one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Cellcept. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Cellcept

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Cellcept.

Tell your doctor if you become pregnant while taking Cellcept. If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning Cellcept therapy, during therapy and for at least six weeks after stopping Cellcept, unless you are not sexually active.

If you are a sexually active male, you are recommended to use condoms during treatment with Cellcept and for 90 days after stopping treatment, even if you have had a vasectomy. Your female partner(s) are recommended to use reliable contraception while you are being treated with Cellcept and for 90 days after you have stopped receiving Cellcept.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

CELLCEPT®

Mycophenolate Mofetil (250mg, 500mg)

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel your medicine is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will need to give you regular blood tests.

Wear protective clothing and a broad-spectrum sunscreen when outdoors.

Medicines that prevent rejection of transplants can increase the risk of skin cancers.

Things you must not do

Do not stop taking Cellcept or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not use Cellcept to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Do not donate blood during therapy and for at least 6 weeks following discontinuation of Cellcept.

Men should not donate semen during therapy and for 90 days following discontinuation of Cellcept.

Things to be careful of

Be careful driving or operating machinery until you know how Cellcept affects you.

However, Cellcept is not expected to affect your ability to drive a car or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cellcept.

Cellcept helps most people who have transplants but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

To stop you rejecting your organ, transplant medications reduce your body's own defence mechanisms. This means your body will not be as good at fighting infection. People taking Cellcept therefore develop more infections than usual.

Patients who receive immunosuppressant medicines may also have a small increase in their risk of developing some types of cancer. You should discuss this with your doctor.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea, constipation, nausea (feeling sick) or indigestion
- stomach, chest, back or other pain
- headache
- fluid in the legs or arms
- urinary infections.

These are the more common side effects of Cellcept. These are mostly mild.

Tell your doctor immediately or go to Accident and Emergency at

your nearest hospital if you notice any of the following:

- signs of other infections e.g. fevers, chills, sore throat or ulcers of the mouth
- unexpected bruising or bleeding
- changes in vision
- signs of anaemia such as excessive tiredness, dizziness or looking pale.

These are serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website nprra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Cellcept

Storage

Store your capsules or tablets in the original package until it is time to take them.

If you store the capsules or tablets out of the original package, they may not keep well.

Keep Cellcept capsules at a temperature below 25°C and Cellcept tablets below 30°C in a cool dry place.

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Always keep the tablets away from direct light and keep the capsules away from moisture.

Do not store Cellcept capsules and tablets or any other medicine, in a bathroom or near a sink.

Do not leave your medicine in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Cellcept where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Cellcept; or the capsules, tablets or suspension have passed their expiry date, ask your pharmacist what to do with any that is left over.

Product Description

Cellcept 250 mg capsules come in packs of 100 capsules.

Cellcept 500 mg tablets come in packs of 50 tablets.

What Cellcept 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 coloured and capsule-shaped, engraved with "Cellcept 500" on one side and "Roche" on the reverse.

Ingredients

Active ingredient:

- Each capsule contains 250 mg of mycophenolate mofetil.
- Each tablet contains 500 mg of mycophenolate mofetil.

Inactive ingredients:

The capsule fill contains:

- pregelatinised maize starch
- croscarmellose sodium
- povidone K90
- magnesium stearate

The tablet contains:

- microcrystalline cellulose
- croscarmellose sodium
- povidone K90
- magnesium stearate
- Opadry Lavender Y-5R-10272-A

MAL number:

Cellcept Capsules 250 mg
(MAL06030803ASZ)
Cellcept Tablets 500 mg
(MAL06030804ASZ)

Manufacturer and product registration holder

Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland
by Roche S.p.A. Milan
production site Segrate, Italy

Product Registration Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya,
Selangor, Malaysia.

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