

Consumer Medicine Information

CellCept®

Mycophenolate mofetil

250 mg capsules

500 mg tablets

500 mg powder for solution for infusion

200 mg/mL oral suspension (when reconstituted)

What is in this leaflet

This leaflet answers some common questions about CellCept capsules, tablets, infusion and oral suspension.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CellCept against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CellCept is used for

CellCept contains the active ingredient mycophenolate mofetil.

CellCept 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.

CellCept may be used together with other medicines known as cyclosporin and corticosteroids.

Your doctor, however, may have prescribed CellCept for another purpose.

Ask your doctor if you have any questions why CellCept has been prescribed for you.

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

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 include swelling, itching, rash, breathing difficulties.
- 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 in patients exposed to 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 of child bearing potential and 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 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 CellCept:

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 one negative pregnancy test prior to starting treatment with CellCept. A second test should be performed 8-10 days later. Repeat pregnancy tests will be performed during routine follow-up visits with your doctor.
- 2. you are breastfeeding or plan to breastfeed**
- 3. you are a sexually active man**
 - you are recommended to use effective contraception during treatment and for 90 days after stopping treatment. 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:**
 - severe kidney disease
 - a history of serious stomach or bowel problems (such as ulcers or bleeding)
 - you have a rare disease such as Lesch-Nyhan or Kelley-Seegmiller syndrome
 - a history of sun spots or skin cancers
- 5. you have phenylketonuria**

- You may not be able to take CellCept oral suspension as it contains a source of phenylalanine.
- 6. you should not donate blood during treatment with CellCept and for at least 6 weeks after stopping treatment**
- 7. men should not donate semen during treatment with CellCept and for at least 90 days after stopping treatment**
- 8. you are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, do so before you start taking CellCept.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with how well CellCept works, or the medicines may not work as well when taken together with CellCept. These medicines include:

- aciclovir, ganciclovir, valaciclovir, valganciclovir – medicines used to treat viral infections
- antacids – a class of medicines used to treat indigestion or heartburn
- azathioprine – a medicine used to suppress the immune system
- calcium-free phosphate binders (such as sevelamer) – a class of 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, may not be as effective as normal. Vaccinations with live vaccines should be avoided
- cholestyramine – a medicine used to treat high cholesterol levels in the blood
- iron supplements - medicines used to treat low iron levels in the blood
- telmisartan – a medicine used to treat high blood pressure and prevent other diseases relating to the heart
- proton-pump inhibitors, used to treat indigestion and stomach ulcers, such as lansoprazole and pantoprazole
- rifampicin, aminoglycosides, ciprofloxacin, cephalosporins, fluroquinolones, penicillins, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole, trimethoprim plus sulfamthoxazole – antibiotic medicines used to treat infections
- tacrolimus – a medicine used to suppress the immune system
- sirolimus and belatacept - medicines used to prevent organ rejection after a transplant
- isavuconazole – a medicine used to treat fungal infections

These medicines may be affected by CellCept or affect how well it works. You may need to use different amounts of the medicine, or you may need to take different medicines or you may need to have additional blood tests when you are taking other 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 within this leaflet.

How much to take

Take CellCept exactly as your doctor has prescribed.

Your doctor will tell you how much CellCept to take each day.

Your treatment may be started with CellCept infusion and changed to tablets or capsules, usually within 14 days. If you need an infusion into a vein a doctor or nurse will administer this.

The normal adult dose to prevent rejection is usually 2 g or 3 g per day, depending on which organ has been transplanted. This should be taken as 1 g or 1.5 g in the morning, and another 1 g or 1.5 g at night.

The normal dose for children and adolescents aged 2 to 18 years to prevent rejection of a kidney transplant depends on their body surface area. Your doctor will determine the daily dose up to a usual maximum of 2 g per day.

Your doctor may adjust your dose depending on your response.

How to take CellCept

Capsules or tablets should be swallowed whole with a glass of water.

CellCept oral suspension should be shaken well every time you use it to ensure you get the right dose. After each dose of suspension, have a glass of water.

CellCept powder for infusion is added to an infusion bag and given as a “drip” into a vein, usually over a period of 2 hours or more.

If a capsule breaks open or a tablet is crushed accidentally then you should wash off any powder thoroughly with soap and water. If the powder gets in your eyes you should rinse it out with plain water.

Avoid getting the suspension or the infusion solution on your skin or in your eyes. If contact with your skin occurs, wash off any liquid thoroughly with soap and water. If the liquid gets in your eyes, rinse it out with plain water.

Taking CellCept oral suspension

You need to use the dispenser and bottle adapter supplied with the medicine to measure the dose. Try not to inhale the dry powder.

1. Shake the closed bottle well for about 5 seconds before each use.
2. Take off the child-resistant bottle cap.
3. Take the dispenser and push the plunger completely down toward the tip of the dispenser.

4. Then put the tip of the dispenser firmly into the opening of the bottle adapter.
5. Turn the whole thing upside down (bottle and dispenser)
6. Pull the plunger down slowly. Keep pulling it out until the desired amount of medicine is in the dispenser
7. Turn the whole thing back around the right way. Holding onto the body of the dispenser, carefully pull the dispenser out of the bottle adapter. The bottle adapter should stay in the bottle.
8. Put the end of the dispenser directly into your mouth and swallow the medicine. Do not mix the medicine with any other liquid when you swallow it.
9. Close bottle with child-resistant cap after each use.
10. Immediately after administration disassemble the dispenser, rinse under running tap water and air dry prior to next use.

When to take it

It is best to take doses approximately 12 hours apart. Your dose can be taken with or without food.

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

How long to take CellCept

CellCept should be taken every day. It is important to keep taking CellCept to ensure your transplanted organ 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.

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency centre if you think that you or anyone else may have taken too much CellCept, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking 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.

Tell your doctor or go to your nearest Accident and Emergency centre immediately if you think you may have an infection (signs may include fever, chills, local inflammation, sore throat or ulcers in the mouth, but there could be other symptoms), any evidence of unexpected bruising or any unexpected bleeding.

These are serious side effects of taking CellCept and you may need urgent medical attention.

CellCept reduces your body's own defence mechanisms to stop you rejecting your transplanted organ. Your body will not be as good at fighting infection as it normally is. People taking CellCept often develop more infections than usual and this could increase the severity of the infection.

Wear protective clothing and a broad-spectrum sunscreen with a high protection factor when outdoors.

Medicines that prevent rejection of transplants, including CellCept, can cause a small increase in the risk of getting cancer, particularly skin cancers. You should discuss this with your doctor if it concerns you.

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

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 may need to give you regular blood tests.

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.

Things to be careful of

Be careful driving or operating machinery until you know how CellCept affects you or if you experience somnolence, confusion, dizziness, tremor or hypotension.

As with many other medicines used to prevent rejection of transplanted organs, CellCept may cause dizziness, drowsiness or light-headedness in some people. Make sure you know how you react to CellCept before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy or light-headed.

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. 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.

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
- headache
- acne
- hair loss or itchy skin
- dizziness or shaking
- inability to sleep (insomnia)

These are more common side effects of CellCept. Mostly, these are mild.

Tell your doctor as soon as possible if you notice any of the following:

- anxiety or depression
- fluid (swelling) in the legs, arms or face
- stomach, back, muscle or other pain
- skin changes, especially changes in moles or freckles
- signs of anaemia such as excessive tiredness, dizziness or looking pale
- cold sores
- lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis

These may be serious side effects. You may require medical treatment.

Tell your doctor immediately, or go to your nearest Accident and Emergency centre if you notice any of the following:

- any signs of infection such as fever, inflammation, sweating, chills or ‘flu-like symptoms, abdominal pain or bloody stools
- unexplained bleeding
- any signs of unexpected bruising
- urinary infection or blood in your urine
- irregular heartbeat or chest pain
- vomiting
- clumsiness
- weakness
- changes in vision or speech
- swelling of the hands, ankles or feet, lymph nodes
- hypersensitivity
- breathing difficulties, pain in the chest, chronic cough with blood

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

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 don’t understand anything in this list.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking CellCept

Storage

Keep your capsules or tablets in the blister pack until it is time to take them.

If you take the capsules or tablets out of the blister pack they may not keep well.

Keep CellCept capsules away from moisture and where the temperature stays below 25°C.

Keep CellCept tablets in the carton where they are protected from light and where the temperature stays below 25°C.

Light will cause the tablets to fade.

Keep CellCept powder for solution for infusion in a cool dry place where the temperature stays below 30°C.

Keep CellCept suspension and tablets in a cool dry place where the temperature stays below 25°C.

Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave CellCept in the car or on windowsills.

Heat and dampness can destroy some medicines.

Discard CellCept Suspension after 60 days.

The suspension only lasts for 60 days after water has been added. After this time it may not work as well.

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 products have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What CellCept looks like

CellCept capsules are oblong, blue on one end and brown on the other, with "CellCept 250" printed in black ink on the cap and "Roche" on the body. They come in packs of 100.

CellCept tablets are lavender coloured and capsule-shaped, with "CellCept 500" engraved on one side and "Roche" on the other. They come in packs of 50.

CellCept oral suspension comes in a bottle with adapter and two oral dispensers. Once the water is added it is a white to off-white liquid. It comes in a single bottle pack.

CellCept powder for solution for infusion is a white to off-white powder. When made up into solution it is slightly yellow. It comes in packs of 4 vials.

Ingredients

Active ingredient

mycophenolate mofetil

- CellCept capsules contain 250 mg of mycophenolate mofetil.
- CellCept tablets contain 500 mg of mycophenolate mofetil
- CellCept oral suspension contains 200 mg/mL of mycophenolate mofetil after the water has been added, to a total volume of 165 mL.
- CellCept infusion solution contains 6 mg/ml mycophenolate mofetil.

Inactive ingredients

Capsules: pregelatinised maize starch, croscarmellose sodium, polyvidone and magnesium stearate. The capsule shell contains gelatin, shellac, potassium hydroxide, indigo carmine, red, yellow and black iron oxide, titanium dioxide, and may also contain sodium lauryl sulphate, silicon dioxide and carboxymethylcellulose.

Tablets: microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate, hypromellose, hydroxypropyl cellulose, titanium dioxide, polyethylene glycol, indigo carmine aluminium lake, red iron oxide.



Suspension: sorbitol, anhydrous colloidal silica, sodium citrate dihydrate, soybean lecithin, mixed fruit flavour, xanthan gum, aspartame, methylparaben and citric acid.

Powder for solution for infusion: polysorbate 80, citric acid and sodium chloride.

CellCept capsules and tablets are gluten and lactose free.

Distributor

CellCept is distributed by:

Roche Products (New Zealand) Limited

PO Box 109113

Newmarket, Auckland 1149

NEW ZEALAND

Medical enquiries: 0800 276 243

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