

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CellCept. 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 the rejection of a transplanted organ and work by stopping your immune system from reacting to the transplanted organ.

There are many different types of medicines used to prevent rejection of a transplanted organ.

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

CellCept is not addictive.

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

Before you take or are given CellCept

When you must not take it

Do not take CellCept if:

1. you have an allergy to:

- CellCept or any of the ingredients listed at the end of this leaflet.
Some of the 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 or hives on the skin

CellCept IV solution should not be given if you have an allergy to polysorbate 80.

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 have taken 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 whether you should start taking this medicine, 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 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 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.
 - you should not donate semen while you are being treated with CellCept and for 90 days after you have stopped receiving CellCept.
- 4. You should not donate blood while you are being treated with CellCept and for at least 6 weeks after you stop receiving CellCept**
 - 5. 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 ulceration or bleeding)
 - rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
 - kidney disease
 - phenylketonuria. You may not be able to take CellCept oral suspension as it is a source of phenylalanine
 - 6. you have allergies to any other medicines, foods, preservatives or dyes**

If you have not told your doctor about any of the above, tell him/her before you start taking CellCept.

Taking other medicines

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

from your pharmacy, supermarket or health food shop.

Some medicines and CellCept may interfere with each other. 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, valaciclovir or valganciclovir, medicines used to treat certain viral infections
- isavuconazole, a medicine used to treat fungal infections
- antacids, medicines used to treat heartburn and indigestion
- cholestyramine, a medicine used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin, medicines used to treat infections
- iron supplements, medicines used to treat low iron levels in the blood
- certain vaccines, (especially live vaccines), medicines that work by causing your body to produce its own protection against an infectious disease
- proton-pump inhibitors, medicines used to treat indigestion and stomach ulcers such as lansoprazole and pantoprazole
- calcium-free phosphate binders (such as sevelamer), medicines used to treat high phosphate levels in the blood

These medicines may be affected by CellCept or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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.

If you do not understand the instructions on the packet ask your doctor or pharmacist for help.

CellCept infusion is only given in a hospital setting by specially trained doctors or nurses.

How much to take

Take CellCept exactly as your doctor has prescribed.

Your doctor will tell you how many CellCept capsules or tablets or how much CellCept suspension to take each day.

Your doctor will work out how much CellCept infusion will be given to you.

CellCept Capsules and Tablets

The dose to prevent organ rejection is usually 1g 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.

CellCept Suspension

Adult

The dose to prevent organ rejection is usually 2 g or 3 g per day depending on which organ has been transplanted. This should be taken as 5 mL or 7.5 mL in the morning and 5 mL or 7.5 mL at night using the oral dispenser provided.

Children

For renal transplant only.

For children 2 to 18 years of age, the dose to prevent organ rejection is dependent on the child's height and weight. The maximum dose is usually 1 g in the morning and 1 g at night (2 g daily).

CellCept Infusion

The dose to prevent organ rejection is usually 2 g to 3 g per day

depending on which organ has been transplanted.

Your doctor may adjust your dose depending on your response.

How to take it

CellCept Capsules and Tablets

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

Do not crush tablets or open or crush capsules. If a capsule breaks open accidentally, wash any powder off your skin with soap and water.

CellCept Suspension

Shake the suspension well before you measure out your dose.

Shaking the bottle will make sure that you get the correct dose.

Just before the suspension was given to you, water was added to the powder in the bottle. The bottle will only be about three-quarters full when you receive it.

After the addition of water, the amount of suspension that can be withdrawn from the bottle is 165 mL. However, each bottle will contain a little more than 165 mL to allow for the small amount of suspension that cannot be withdrawn from the bottle with the oral dispenser.

After each dose of the suspension have a glass of water.

If you accidentally spill the suspension on yourself, wash off any liquid thoroughly with soap and water.

Taking the medicine

You need to use the dispenser and bottle adapter supplied with the medicine to measure the dose. Take care not to let the made-up medicine get into your eyes. If this happens, rinse your eyes with plain water. Take care not to let the made-up medicine get onto your skin. If this happens, wash the area thoroughly with soap and water.

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.

CellCept Infusion

CellCept is added to an infusion bag and given as a 'drip' into a vein, usually over a period of two or more hours.

It is only given in a hospital setting and doses are usually approximately 12 hours apart.

If contact with the infusion solution occurs, wash off any liquid thoroughly with soap and water.

When to take CellCept

It is best to take doses of CellCept capsules, tablets or suspension approximately 12 hours apart.

Take your medicine at about the same time each day.

Taking CellCept at the same time each day will have the best effect. It

will also help you remember when to take it.

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 for as long as your doctor tells you.

If you are receiving CellCept infusion, your doctor will most likely change this medication to CellCept capsules, tablets or suspension once you are able to take these.

If you forget to take CellCept tablets, capsules or suspension

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 take a double dose to make up for the dose that you missed.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CellCept. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using CellCept

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CellCept.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking CellCept.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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 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.

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 broad-spectrum sunscreen when outdoors.

Medicines that prevent the rejection of transplanted organs 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 use CellCept to treat any other complaints unless your doctor tells you to.

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

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

Do not crush CellCept tablets or open CellCept capsules.

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.

CellCept may 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.

This medicine helps most people who have organ transplants, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 receiving CellCept therefore develop more infections than usual and this could increase the severity of the infections.

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 increase chance of side effects occurring due to immunosuppression.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

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

- diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion
- stomach, chest or back pain
- headache
- urinary infections

The above list includes the more common side effects of CellCept.

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, ulcers of the mouth, abdominal pain or bloody stools.
- unexpected bruising or bleeding
- signs of anaemia such as excessive tiredness, dizziness or looking pale
- swelling of the hands, ankles or feet, lymph nodes
- hypersensitivity
- breathing difficulties, pain in the chest, chronic cough with blood.

The above list includes 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. Other side effects may occur in some people and there may be some others that are not yet known.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using CellCept

Storage

CellCept Capsules and Tablets

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

CellCept Suspension

Discard the suspension after 60 days.

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

Keep CellCept suspension in a cool dry place where the temperature stays below 25°C. It may be stored in a refrigerator but should not be frozen.

CellCept Infusion

The infusion will be stored by the hospital pharmacy or on the ward until it is time to use it.

Do not store CellCept or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where 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 expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

Availability

CellCept 250 mg capsules come in packs of 100 capsules.

CellCept 500 mg tablets come in packs of 50 tablets.

CellCept 200 mg/mL suspension comes in a 225 mL bottle with an adapter and two oral dispensers.

CellCept 500 mg infusion comes in packs of 4 vials. CellCept vials will be kept in the hospital pharmacy or on the ward.

What CellCept capsules look 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.

Ingredients

CellCept capsules contain 250 mg of mycophenolate mofetil as the active ingredient.

Inactive ingredients:

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

The capsule shell contains:

- Gelatine
- Sodium lauryl sulphate
- Shellac

- Potassium hydroxide
- Silicon dioxide

The dyes in the capsule shell are:

- Indigo carmine (132)
- Iron oxide red (172)
- Titanium dioxide (171)
- Iron oxide yellow (172)
- Iron oxide black (172)

CellCept capsules are gluten and lactose free.

What CellCept tablets look like

CellCept tablets are lavender coloured and capsule shaped, engraved with 'CellCept 500' on one side and 'Roche' on the other.

Ingredients

CellCept tablets contain 500 mg of mycophenolate mofetil as the active ingredient.

Inactive ingredients:

- Microcrystalline cellulose (460)
- Croscarmellose sodium
- Povidone
- Magnesium stearate (470)
- Talc (553)
- The proprietary ingredient Opadry Lavender Y-5R-10272-A (includes 464, 171, 132 and 172).

CellCept tablets are gluten and lactose free.

What CellCept suspension looks like

CellCept suspension is a white to off-white powder.

Ingredients

CellCept suspension contains 1 g of mycophenolate mofetil per 5 mL as the active ingredient when reconstituted.

Inactive ingredients:

- Sorbitol (420)
- Silicon dioxide (551)
- Sodium citrate (331)
- Soybean lecithin

- Mixed fruit flavour
- Xanthan gum (415)
- Aspartame (951)
- Methyl hydroxybenzoate (218)
- Citric acid anhydrous (330)

What CellCept infusion looks like

CellCept infusion is a sterile white to off-white powder in a clear glass vial. It will be made up into an infusion bag before being given to you. The solution in the infusion bag should be clear to slightly yellow.

Ingredients

CellCept infusion contains 500 mg of mycophenolate mofetil as the hydrochloride salt.

Inactive ingredients:

- Polysorbate 80
- Citric acid (330)
- Sodium chloride

Manufacturer

CellCept is distributed in Australia by:

Roche Products Pty Limited
 ABN 70 000 132 865
 Level 8, 30-34 Hickson Road
 Sydney NSW 2000
 AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

CellCept 250 mg capsules AUST R 67313

CellCept 500 mg tablets AUST R 82372

CellCept 200 mg/mL suspension AUST R 72582

CellCept 500 mg vials AUST R 68233

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CellCept®

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