CellCept®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CellCept?

CellCept contains the active ingredient mycophenolate mofetil. CellCept is used to prevent the rejection of a transplanted organ.

For more information, see Section 1. Why am I taking CellCept? in the full CMI.

2. What should I know before I take CellCept?

Do not use if you have ever had an allergic reaction to mycophenolate mofetil a related medicine called mycophenolic acid, or any of the ingredients listed at the end of the CMI. Do not use if you are pregnant or breast feeding, or if you are a woman who could become pregnant and you are not using two reliable forms of contraception.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take CellCept? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CellCept and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take CellCept?

- 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.

More instructions can be found in Section 4. How do I take CellCept? in the full CMI.

5. What should I know while taking CellCept?

Things you should do	• Tell any doctor,

	surgeon, anaesthetist, dentist or pharmacist that is treating you that you are using CellCept. • Wear protective clothing and broad-spectrum sunscreen when outdoors.	
Things you should not do	• Do not stop using this medicine without first checking with your doctor. • Do not take any other medicines - whether they require a prescription or not -	

	without first telling your doctor or consulting with a pharmacist.	
Driving or using machines	• Be careful driving or operating machinery until you know how CellCept affects you, or if you experience somnolence (drowsiness) (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).	
Looking after your medicine	• Keep CellCept capsules and tablets in a cool dry place where the	

	temperature stays below 25°C. • Keep CellCept suspension in a cool dry place where the temperature stays below 30°C. It may be stored in a refrigerator but should not be frozen.

For more information, see Section 5. What should I know while taking CellCept? in the full CMI.

6. Are there any side effects?

More common side effects include diarrhoea, constipation, nausea, vomiting, indigestion, pain in the stomach, chest or back, headache, and urinary infection. Less common but possibly serious side effects include infections, bruising, anaemia, swelling of the hands, ankles or lymph nodes (glands), chronic cough with blood and allergic reactions such as chest tightness, wheezing, difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat

with difficulty breathing, skin rash, itching or hives (raised red patches of skin that are often very itchy).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CellCept®

Active ingredient: Mycophenolate mofetil

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CellCept. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CellCept.**

Where to find information in this leaflet:

1. Why am I taking CellCept?
2. What should I know before I take CellCept?
3. What if I am taking other medicines?
4. How do I take CellCept?
5. What should I know while taking CellCept?
6. Are there any side effects?
7. Product details

1. Why am I taking CellCept?

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 taken together with other medicines known as cyclosporin and corticosteroids.

2. What should I know before I take CellCept?

Warnings

Do not take CellCept if:

- **you are allergic to mycophenolate mofetil, a related medicine called mycophenolic acid, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of a serious allergic reaction may include:
  - chest tightness, wheezing or difficulty breathing
  - severe dizziness or light-headedness
  - swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
  - skin rash, itching or hives (raised red patches of skin that are often very itchy)
  -

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

- **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.

- **you are breast feeding**
  - CellCept can pass into human breast milk and could cause serious side effects in your baby if you breastfeed.
- **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 6 months after stopping CellCept, unless you are not sexually active.
- **the package is torn or shows signs of tampering**
- **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.

Check with your doctor if 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

- **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.
  - have allergies to any other medicines, foods, preservatives or dyes.

You should not donate blood while you are being treated with CellCept and for at least 6 weeks after you stop receiving CellCept.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. If you are a woman of childbearing 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.

Talk to your doctor if you are breast feeding or intend to breast feed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CellCept and affect how it 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, valaciclovir or valganciclovir used to treat certain viral infections

- isavuconazole - used to treat fungal infections
- antacids - used to treat heartburn and indigestion
- colestyramine - used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin and other medicines used to treat infections
- iron supplements - 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 such as lansoprazole and pantoprazole - used to treat indigestion and stomach ulcers
- telmisartan – used to treat high blood pressure
- calcium-free phosphate binders (such as sevelamer) - 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CellCept.

4. How do I take CellCept?

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 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.

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

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.

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.

Do not use if the packaging is damaged, or any supplies provided are missing or damaged. Contact your doctor or pharmacist if both oral dispensers are missing or damaged (e.g. a dosage marking is no longer clearly visible or the dispenser becomes difficult to use). They will advise you on how to continue to take your medication.

Wash hands before and after using the dispenser.

Taking the medicine

You need to use the dispenser and bottle adapter supplied with the medicine to measure the dose.

1. Shake the closed bottle well for about 5 seconds before each use. Shaking the bottle will make sure that you get the correct dose.
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 ensure all the medicine is swallowed.

- Do not mix the medicine with any other liquid when you swallow it.
- To avoid choking or vomiting, ensure you are in an upright body position, place the oral dispenser into the mouth with the tip along either cheek, slowly push the plunger all the way down, and do not squirt forcefully into the back of the throat.

9. After swallowing the medicine have a glass of water.
10. Close bottle with child-resistant cap after each use.
11. Immediately after administration take the dispenser to pieces, rinse under running tap water until all residue is removed and air dry prior to next use.

- Do not sterilize the dispenser, or put into boiling water, to avoid damage of the dispenser.
- Do not use solvent-containing wipes for cleaning.
- Do not use cloths or wipes for drying.
- Do not throw away the dispenser as it needs to be used multiple times.

12. For storage, keep dispenser dry and away from sunlight.

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.

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 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 CellCept

If you think that you have taken too much CellCept, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking CellCept?

Things you should 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 childbearing potential, you must use two reliable forms of contraception at the same time before beginning CellCept therapy, during therapy and for at least 6 months 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 should 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.

Driving or using machines

Be careful driving or operating machinery until you know how CellCept affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

CellCept may affect your ability to drive a car or operate machinery.

Looking after your medicine

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.

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 30°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.

When to discard your medicine

If your doctor tells you to stop taking CellCept, or the expiry date has passed, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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 increased chance of side effects occurring due to immunosuppression.

Less serious side effects

Less serious side effects	What to do
• diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion • stomach, chest, muscle or back pain • headache • urinary infections • acne • hair loss or itchy skin	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• swelling of the hands, ankles or feet, lymph nodes (glands) • inability to sleep (insomnia) • signs of allergic reaction (chest tightness, wheezing or difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing, skin rash, itching or hives appearing as raised red patches of skin that are often very itchy) • 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

CellCept Capsules

CellCept 250 mg capsules come in packs of 100 capsules.

CellCept capsules are not currently marketed in Australia

Active ingredient **(main ingredient)**	Mycophenolate mofetil

Other ingredients **(inactive ingredients)**	• Pregelatinised maize starch • Croscarmellose sodium • Povidone • Magnesium stearate (470) The capsule shell contains: • Gelatin • Sodium lauryl sulfate • 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)
Potential allergens	CellCept capsules are gluten and lactose free.

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.

AUST R 67313

CellCept Tablets

CellCept 500 mg tablets come in packs of 50 tablets.

CellCept tablets are not currently marketed in Australia.

Active ingredient (main ingredient)	Mycophenolate mofetil
Other ingredients (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).
Potential allergens	CellCept tablets are gluten and lactose free.

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

AUST R 82372

CellCept Suspension

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

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

Active ingredient **(main ingredient)**	Mycophenolate mofetil
Other ingredients **(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)
Potential allergens	Contains aspartame (a source of phenylalanine), sorbitol, soya bean products and hydroxybenzoates. Maximum recommended daily dose of CellCept (3 g) contains 5.99 g sorbitol. Products containing sorbitol may have a

	laxative effect or cause diarrhoea.

CellCept suspension is a white to off-white powder. Once the water is added it is a white to off-white liquid.

AUST R 72582

CellCept Infusion

CellCept 500 mg infusion comes in packs of 4 vials.

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

CellCept vials will be kept in the hospital pharmacy or on the ward.

Active ingredient **(main ingredient)**	Mycophenolate mofetil
Other ingredients **(inactive ingredients)**	• Polysorbate 80 • Citric acid (330) • Sodium chloride
Potential allergens	N/a

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.

AUST R 68233

Who distributes CellCept

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.

This leaflet was prepared in October 2026.