

# CellCept<sup>®</sup> Capsules, Tablets and Suspension



pronounced (Sell-Sept)

contains the active ingredient mycophenolate mofetil

## Consumer Medicine Information

There are many different types of medicines used to prevent transplant rejection.

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 about why CellCept has been prescribed for you.**

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

CellCept is not addictive.

## 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. **the package is torn or shows signs of tampering.**

3. **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**

It is not known whether CellCept is harmful to an unborn baby when taken by a pregnant woman. There have been cases of birth defects reported in patients exposed to CellCept in combination with other immunosuppressants during pregnancy. If there is a need to take CellCept when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

2. **you are breast-feeding or plan to breast-feed**

It is not known whether CellCept passes into breast milk. Your doctor will discuss the risks and benefits of taking CellCept if you are breast-feeding.

3. **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).

## What is in this leaflet

This leaflet answers some common questions about CellCept capsules, tablets and 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 they expect it will have 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.

- phenylketonuria. CellCept suspension is a source of phenylalanine.
  - kidney disease.
- 4. 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 prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with CellCept. These medicines include:

- aciclovir or ganciclovir, medicines used to treat viral infections
- antacids, medicines used to treat heartburn and indigestion
- azathioprine, a medicine used to suppress the immune system
- 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
- iron supplements, medicines used to treat low iron 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
- tacrolimus, a medicine used to suppress the immune system

- sirolimus, a medicine used to prevent organ rejection after a transplant.

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.**

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## **How to take CellCept**

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**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, or how much CellCept suspension to take each day.

### **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 rejection is dependent on your child's height and weight. The maximum dose is usually 1 g in the morning and 1 g at night (2 g daily).

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 glass of water.**

**If a capsule breaks open accidentally, wash off any powder thoroughly with soap and water.**

### **CellCept Suspension**

**Shake the suspension well before you measure out your dose.**

This will ensure you get the right dose every time.

Just before the suspension was given to you, water was added to the powder in the bottle to make the suspension. 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 suspension, have a glass of water.

**If you accidentally spill the suspension on yourself, wash off**



any liquid thoroughly with soap and water.

### ***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 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 Poisons Information Centre (telephone 13 11 26), 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.**

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## **While you are taking CellCept**

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### ***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.**

It is important to take effective contraceptive measures four weeks before you commence taking CellCept, while you are taking CellCept and for six weeks after you stop taking 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 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 a pharmacist.**

### ***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.

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## **Side effects**

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**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. Mostly these are 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
- clumsiness
- weakness
- changes in vision or speech
- signs of anaemia such as excessive tiredness, dizziness or looking pale.

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.**

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.**

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## After taking CellCept

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### 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 30 °C.**

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

Light will cause CellCept tablets to fade.

#### CellCept Suspension

**Discard the 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 suspension in a cool dry place where the temperature stays below 25 °C.**

**Do not freeze the suspension.**

It may, however, be kept in the fridge (2 – 8 °C).

**Do not store CellCept capsules, tablets or suspension, 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.**

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## Product description

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### 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 adapter and two oral dispensers.

CellCept is also available as a 500 mg infusion solution (packs of 4 vials).

### 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**

### **Active ingredient:**

- Each capsule contains 250 mg of mycophenolate mofetil.

### Inactive ingredients:

The capsule fill contains:

- pregelatinised maize starch
- croscarmellose sodium
- povidone
- magnesium stearate (470).

The capsule shell contains:

- gelatin
- sodium lauryl sulfate
- shellac
- potassium hydroxide
- silicon dioxide (551).

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 reverse.

## **Ingredients**

### **Active ingredient:**

- Each tablet contains 500 mg of mycophenolate mofetil.

### Inactive ingredients:

- microcrystalline cellulose (460)
- croscarmellose sodium
- povidone
- magnesium stearate (470)

- talc (553)
- the proprietary ingredients: Opadry Lavender Y-5R-10272-A (includes 464, 171, 132 & 172).

CellCept tablets are gluten and lactose free.

### **What CellCept Suspension looks like**

CellCept suspension is a white to off-white liquid.

## **Ingredients**

### **Active ingredient:**

- The suspension contains 1 g of mycophenolate mofetil per 5 mL.

### 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).

AUST R 82372

- CellCept 200 mg/mL suspension

AUST R 72582

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## **Distributor**

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CellCept is distributed by:

Roche Products Pty Limited  
ABN 70 000 132 865  
4-10 Inman Road  
Dee Why NSW 2099  
AUSTRALIA

Customer enquiries: 1 800 233 950

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