

CellCept® Infusion



pronounced (Sell-Sept)

contains the active ingredient mycophenolate mofetil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CellCept infusion.

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 using CellCept against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What CellCept is given 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.

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 are given CellCept

When you must not receive it

You must not receive CellCept if:

- 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.

If you are not sure if you should be receiving CellCept, talk to your doctor.

Before you start to receive 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 used by a pregnant woman. In humans, 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 use 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)
- 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 for prevention of organ rejection after a transplant.

These medicines may be affected by CellCept, or may affect how well it works. You may need to receive 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 receiving CellCept.

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

How CellCept is given

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

How much is given

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 CellCept is given

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

Avoid all contact with the infusion solution.

If such contact occurs, wash off any liquid thoroughly with soap and water, rinse eyes with plain water.

When you will receive CellCept

It is best if doses are given approximately every 12 hours.

How long you will receive CellCept for

CellCept should be given every day. It is important to keep using CellCept to ensure your new transplant keeps working properly.

Your doctor will most probably change this medication to CellCept capsules, tablets or

suspension once you are able to take these.

While you are receiving CellCept

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are receiving CellCept.

Tell your doctor if you become pregnant while receiving CellCept.

It is important to take effective contraceptive measures four weeks before you receive CellCept, while you are receiving CellCept and for six weeks after you stop receiving CellCept.

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 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.

However, CellCept is not expected to affect your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving 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 receiving 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 side effects occurring.

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.

Product description

Availability

CellCept 500 mg infusion comes in packs of 4 vials.

CellCept vials will be kept in the hospital pharmacy or on the ward below 30 °C.

CellCept is also available as 250 mg capsules, 500 mg tablets and 200 mg/mL suspension.

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.

Solution in the infusion bag should be clear to slightly yellow.

Ingredients

Active ingredient:

- Each vial contains 500 mg of mycophenolate mofetil as the hydrochloride salt.

Inactive ingredients:

- polysorbate 80
- citric acid, anhydrous
- sodium chloride.

Distributor

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 Number

- CellCept 500 mg vials
AUST R 68233

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