

MycoCell

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 MycoCell?

MycoCell contains the active ingredient mycophenolate mofetil. It belongs to a group of immunosuppressants, which are used to prevent the rejection of a transplanted organ and work by stopping your immune system from reacting to the transplanted organ.

For more information, see Section [1. Why am I using MycoCell?](#) in the full CMI.

2. What should I know before I use MycoCell?

Do not use if you have ever had an allergic reaction to MycoCell or any of the ingredients listed at the end of the CMI.

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 use MycoCell?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MycoCell 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 use MycoCell?

Take MycoCell exactly as your doctor has prescribed. Your doctor will tell you how much MycoCell suspension to take each day.

More instructions can be found in Section [4. How do I use MycoCell?](#) in the full CMI.

5. What should I know while using MycoCell?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MycoCell• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MycoCell• Stop taking MycoCell and contact your doctor immediately if you become pregnant while you are taking MycoCell
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not use it to treat any other complaints unless your doctor tells you to
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how MycoCell affects you• MycoCell may affect your ability to drive a car or operate machinery
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep MycoCell 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.

For more information, see Section [5. What should I know while using MycoCell?](#) in the full CMI.

6. Are there any side effects?

- common side effects: headache, nausea or vomiting, diarrhoea or constipation, urinary infections, stomach, chest or back pain
- Serious side effects: 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

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.

MycoCell

mycophenolate mofetil

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. [Why am I using MycoCell?](#)
2. [What should I know before I use MycoCell?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use MycoCell?](#)
5. [What should I know while using MycoCell?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using MycoCell?

MycoCell contains the active ingredient mycophenolate mofetil.

MycoCell 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.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

MycoCell is not addictive.

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

2. What should I know before I use MycoCell?

Warnings:

Do not use MycoCell if you are allergy to:

- any medicine containing mycophenolate
- 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.

Do not take MycoCell, if you are pregnant, think you may be pregnant, or intend to become pregnant.

- MycoCell 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 MycoCell during pregnancy.
- You must tell your doctor if you are pregnant or plan to become pregnant.

Do not take MycoCell if you are breast-feeding

MycoCell may pass into human breast milk and could cause serious side effects in your baby if you breastfeed.

Do not take MycoCell if 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 MycoCell therapy, during therapy and for at least six weeks after stopping MycoCell, unless you are not sexually active.

Do not take MycoCell after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

- If it has expired or is damaged, return it to your pharmacist for disposal.

- **If you are not sure whether you should start taking this medicine, talk to your doctor.**

Before you start to take it

Tell your doctor if 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 MycoCell.
- Repeat pregnancy tests will be performed during routine follow up visits with your doctor.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Tell 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 MycoCell and for 90 days after you have stopped receiving MycoCell.
- you should not donate semen while you are being treated with MycoCell and for 90 days after you have stopped receiving MycoCell.

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

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- sun spots or skin cancers
- low blood counts of neutrophils (a type of white blood cell)
- serious problems with your stomach or bowel, such as ulcers or bleeding
- Lesch-Nyhan or Kelley-Seegmiller syndrome (a rare hereditary disorder that affects males only and is caused by a deficiency of a specific (HGPRT) enzyme).
- kidney disease
- Phenylketonuria. You may not be able to take MycoCell oral suspension as it is a source of phenylalanine

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MycoCell

3. What if I am taking other medicines?

Taking other medicines

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

Some medicines and MycoCell 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
- aciclovir, 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
- colestyramine, 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 MycoCell 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.

4. How do I use MycoCell?

Take MycoCell exactly as your doctor has prescribed.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

How much to take / use

Take MycoCell exactly as your doctor has prescribed.

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

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).

How to take it

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 165mL.

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.

Drink a glass of water after swallowing the medicine

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 of MycoCell suspension approximately 12 hours apart.

Take your medicine at about the same time each day.

Taking MycoCell 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 it

Continue taking your medicine for as long as your doctor tells you.

MycoCell should be taken every day. It is important to keep taking MycoCell to ensure your new transplant keeps working properly.

If you forget to take it

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 your medicine 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)

MycoCell should be taken every day. It is important to keep taking MycoCell to ensure your new transplant keeps working properly.

If you think that you have used too much MycoCell, 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 using MycoCell?

Things you should do

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

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

It may affect other medicines used during surgery.
Stop taking MycoCell and contact your doctor immediately if you become pregnant while you are taking MycoCell

If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning MycoCell therapy, during therapy and for at least six weeks after stopping MycoCell, 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 MycoCell and for 90 days after you have stopped receiving MycoCell

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you have any medical test, tell your doctor that you are taking MycoCell

This medicine may affect the results of some tests.
Tell your doctor if you believe that MycoCell is not helping your condition.

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

Your doctor may think it is not working effectively and change your treatment unnecessarily.

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 MycoCell or lower the dosage unless you have discussed it with your doctor.

Do not take MycoCell 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 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MycoCell affects you or if you experience somnolence, confusion, dizziness, tremor or hypotension.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep MycoCell 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.

Do not store MycoCell 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.

When to discard your medicine.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date

6. Are there any side effects?

To stop you rejecting your organ, transplant medications reduce your body's own defense mechanisms.

This means your body will not be as good at fighting infection. People receiving MycoCell 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 increase chance of side effects occurring due to immunosuppression.

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

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.

Common side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion• stomach, chest or back pain• headache• urinary infections	Tell your doctor or pharmacist if you notice any of the following and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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 <p>The above list includes serious side effects that may require medical attention. Serious side effects are rare.</p>	All your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may 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

What MycoCell contains

Active ingredient (main ingredient)	MycoCell suspension contains 1 g of mycophenolate mofetil per 5 mL as the active ingredient when reconstituted.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sorbitol• Silicon dioxide• Sodium citrate• Soybean lecithin• MM16 N&A Gum Fruit FL SD #912• Xanthan gum• Aspartame• Methyl hydroxybenzoate• Citric acid anhydrous

Do not take this medicine if you are allergic to any of these ingredients.

What MycoCell looks like

MycoCell suspension is a white to off white powder.

Who distributes MycoCell

Pharmacor Pty Ltd.
Suite 803, Level 8, Tower A,
The Zenith, 821 Pacific Highway,
Chatswood, NSW, 2067
Australia
www.pharmacor.com.au

MycoCell 200 mg/mL Suspension
AUST R 363232

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