

MycoCept

Mycophenolate Mofetil 500 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MycoCept.

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 MycoCept 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 MycoCept is used for

MycoCept contains the active ingredient mycophenolate mofetil.

MycoCept 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.

MycoCept belongs to a new group of these medicines.

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

Your doctor, however, may have prescribed MycoCept for another purpose.

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

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

MycoCept is not addictive.

Before you take MycoCept

When you must not take it

Do not take MycoCept if:

1. **You have had an allergic reaction to MycoCept 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 face, lips, tongue or other parts of the body
- rash, itching, hives on the skin

2. **You are pregnant.**

MycoCept 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 MycoCept during pregnancy.

You must tell your doctor if you are pregnant or plan to become pregnant.

3. **You are breastfeeding.**

MycoCept 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 MycoCept therapy, during therapy and for at least six weeks after stopping MycoCept, 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 if you should be taking MycoCept, talk to your doctor.

Before you start to take it

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 MycoCept.

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 MycoCept and for 90 days after you have stopped receiving MycoCept. You should not donate semen while you are being treated with MycoCept and for 90 days after you have stopped receiving MycoCept.

4. You should not donate blood while you are being treated with MycoCept and for 6 weeks after you stop receiving MycoCept.

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 ulcers or bleeding)
- rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelly-Seegmiller syndrome
- kidney disease

6. 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 MycoCept.

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 MycoCept. These medicines include:

- azathioprine, tacrolimus and sirolimus, medicines used to

suppress the immune system which can be used to prevent organ rejection after a transplant

- aciclovir or ganciclovir, valaciclovir or valganciclovir, medicines used to treat 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 MycoCept 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 MycoCept.

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

How to take MycoCept

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 MycoCept exactly as your doctor has prescribed.

Your doctor will tell you how many tablets, to take each day.

MycoCept

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. MycoCept is not suitable for paediatric patients whose body surface area is <1.50 m². Patients with a body surface area >1.5 m² may be dosed with MycoCept at a dose of 1 g twice daily (2 g daily dose).

Your doctor may adjust your dose depending on your response.

How to take it

MycoCept

Swallow the tablets whole with a glass of 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 MycoCept.

How long to take MycoCept

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

Continue taking MycoCept until your doctor tells you to stop.

If you forget to take MycoCept

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 MycoCept. 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.

While you are taking MycoCept

Things you must do

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking MycoCept.

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 MycoCept.

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

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 MycoCept or change the dose without first checking with your doctor.

Do not use MycoCept to treat other complaints unless your doctor says to.

Do not give MycoCept 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 MycoCept tablets.

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 MycoCept affects you or if you experience somnolence, confusion, dizziness, tremor, or hypotension.

MycoCept 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 MycoCept.

MycoCept helps most people who have organ 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 MycoCept 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 occurring due to immunosuppression.

Do not be alarmed by this 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 if you notice any of the following and they worry you:

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

These are the more common side effects of MycoCept. 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, 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, feet or lymph nodes
- Hypersensitivity
- Breathing difficulties, pain in the chest, chronic cough with blood.

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.

After taking MycoCept

Storage

MycoCept

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Keep MycoCept in cool dry place where the temperature stays below 25°C. Protect from light.

Always keep the tablets away from direct light.

Light will cause MycoCept to fade.

Do not store MycoCept 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 MycoCept 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 MycoCept; or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

Availability

MycoCept is available in blister packs of 50 tablets.

What MycoCept looks like

MycoCept are purple coloured, capsule shaped, biconvex, film coated tablets debossed 'AHI' on one side and '500' on other side.

Ingredients

Active ingredient:

Each tablet contains 500 mg of Mycophenolate mofetil.

Inactive ingredients:

- Microcrystalline cellulose
- Povidone
- Hypromellose
- Croscarmellose sodium
- Purified talc
- Magnesium stearate
- Opadry complete film coating system 03B50110 PURPLE (PI number: 12853) includes Hypromellose, Titanium dioxide (CI No. 77891), Macrogol 400, Iron oxide red (CI77491), Indigo carmine (CI73015) and Iron oxide black (CI77499)

MycoCept is gluten and lactose free.

Australian Registration Number

MycoCept:
AUST R 235571

Name and Address of the Sponsor

Arrow Pharma Pty. Ltd
15-17 Chapel St
Cremorne VIC 3121
Australia
www.arrowpharma.com.au

Date of Preparation

September 2019