

Pharmacor Mycophenolate 500

Mycophenolate Mofetil 500 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pharmacor Mycophenolate 500.

It does not contain all the available information.

It does not take the place of talking to your doctor, pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pharmacor Mycophenolate 500 against the benefits expected 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 Pharmacor Mycophenolate 500 is used for

Pharmacor Mycophenolate 500 contains the active ingredient mycophenolate mofetil.

Pharmacor Mycophenolate 500 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 rejection of transplanted organ.

Pharmacor Mycophenolate 500 may be used together with other medicines known as cyclosporin and corticosteroids.

Ask your doctor if you have any questions about why Pharmacor Mycophenolate 500 has been prescribed for you.

Your doctor, however, may have prescribed Pharmacor Mycophenolate 500 for another reason.

Pharmacor Mycophenolate 500 is not addictive

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

Before you take or are given Pharmacor Mycophenolate 500

When you must not take it

Do not take Pharmacor Mycophenolate 500 if:

1. You have an allergy to :

- Pharmacor Mycophenolate 500 or any of the ingredients listed at the end of the 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

Pharmacor Mycophenolate 500 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 Pharmacor Mycophenolate 500 during pregnancy.

- You must tell your doctor if you are pregnant or plan to become pregnant.
- 3. You are breastfeeding**
Pharmacor Mycophenolate 500 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 Pharmacor Mycophenolate 500 therapy, during therapy and for at least six weeks after stopping Pharmacor Mycophenolate 500, 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 this medicine, 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 Pharmacor Mycophenolate 500.
- 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 Pharmacor Mycophenolate 500 and for 90 days after you have stopped receiving Pharmacor Mycophenolate 500.

4. 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 ulceration or bleeding), rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
 - kidney disease
 - phenylketonuria.
- 5. You have allergies to any other medicines, foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell him/her before you start-taking Pharmacor Mycophenolate 500.

Taking other medicines

Tell your doctor or pharmacist 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 Pharmacor Mycophenolate 500. These medicines include:

- azathioprine, tacrolimus and sirolimus, medicines used to suppress the immune system which can be used to prevent organ rejection after the transplant.
- aciclovir or ganciclovir, valaciclovir or valganciclovir, medicines used to treat viral 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, (specially 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 Pharmacor Mycophenolate 500 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 or pharmacist has more information on medicines to be careful with or avoid while taking Pharmacor Mycophenolate 500.

How to take Pharmacor Mycophenolate 500

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Take Pharmacor Mycophenolate 500 exactly as your doctor has prescribed.

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

Pharmacor Mycophenolate 500

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.

Your doctor may adjust your dose depending on your response.

How to take it

Pharmacor Mycophenolate 500

Swallow the tablets whole with a glass of water.

Do not crush or open tablets. If a tablet breaks open accidentally, wash off any powder off your skin with soap and water.

When to take it

It is best to take doses approximately 12 hours apart.

Take your medicine at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take your Pharmacor Mycophenolate 500.

How long to take Pharmacor Mycophenolate 500

Pharmacor Mycophenolate 500 should be taken every day. It is important to keep taking Pharmacor Mycophenolate 500 to ensure your new transplant keeps working properly.

Continue taking Pharmacor Mycophenolate 500 until your doctor tells you to stop.

If you forget to take Pharmacor mycophenolate 500

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 Pharmacor Mycophenolate 500. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Pharmacor Mycophenolate 500

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pharmacor Mycophenolate 500.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Pharmacor Mycophenolate 500. 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 Pharmacor Mycophenolate 500.

If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before

beginning Pharmacor Mycophenolate 500 therapy, during therapy and for at least six weeks after stopping Pharmacor Mycophenolate 500, 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 Pharmacor Mycophenolate 500 and for 90 days after you have stopped receiving Pharmacor Mycophenolate 500.

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 Pharmacor Mycophenolate 500 or change the dose without first checking with your doctor.

Do not use Pharmacor Mycophenolate 500 to treat other complaints unless your doctor tells you to.

Do not give Pharmacor Mycophenolate 500 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 a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Pharmacor Mycophenolate 500 affects you.

However, Pharmacor Mycophenolate 500 is not expected to 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 Pharmacor Mycophenolate 500.

Pharmacor Mycophenolate 500 helps most people who have transplants but it may have unwanted side effects in some 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 Pharmacor Mycophenolate 500 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 the following 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, or back pain
- headache
- urinary infections

The above list includes the more common side effects of Pharmacor Mycophenolate 500.

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
- Signs of anaemia such as excessiveness tiredness, dizziness or looking pale
- Swelling of the hands, ankles or feet

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. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Pharmacor Mycophenolate 500

Storage

Pharmacor Mycophenolate 500 Tablets

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 Pharmacor Mycophenolate 500 in a cool dry place where the temperature stays below 25°C. Protect from Light

Do not store Pharmacor Mycophenolate 500 or any other medicine, in a bathroom or near a sink. Do not leave it on window sills or in the car.

Heat and dampness can destroy some medicines.

Keep Pharmacor Mycophenolate 500 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 Pharmacor Mycophenolate 500; or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

Availability

Pharmacor Mycophenolate 500 is available in blister packs of 50 Tablets and 150 Tablets.

What Pharmacor Mycophenolate 500 looks like

Pharmacor Mycophenolate 500 tablets are purple colored, 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
- Hydroxypropylcellulose
- 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).

Pharmacor Mycophenolate 500 tablets are gluten and lactose free.

Manufacturer

Pharmacor Mycophenolate 500 is distributed by:

PHARMACOR LIMITED

Suite 501, 7 Oaks Avenue
DEE WHY NSW 2099
Australia

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

Pharmacor Mycophenolate 500
AUST R 164418

DATE OF TGA APPROVAL

21st November 2011

DATE OF MOST RECENT AMENDMENT

17th December 2015