

PHARMACOR MYCOPHENOLATE 250

(Mycophenolate Mofetil capsules 250 mg)

contains the active ingredient mycophenolate mofetil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PHARMACOR MYCOPHENOLATE 250. 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 PHARMACOR MYCOPHENOLATE 250 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 250 is used for

PHARMACOR MYCOPHENOLATE 250 contains the active ingredient mycophenolate mofetil.

PHARMACOR MYCOPHENOLATE 250 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 a transplanted organ.

PHARMACOR MYCOPHENOLATE 250 may be used together with other medicines known as ciclosporin and corticosteroids.

Ask your doctor if you have any questions about why PHARMACOR MYCOPHENOLATE 250 has been prescribed for you.

Your doctor may have prescribed PHARMACOR MYCOPHENOLATE 250 for another reason.

PHARMACOR MYCOPHENOLATE 250 is not addictive

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

Before you take or are given PHARMACOR MYCOPHENOLATE 250

When you must not take it

Do not take PHARMACOR MYCOPHENOLATE 250 if:

1. You have an allergy to:

- PHARMACOR MYCOPHENOLATE 250 or any of the ingredients listed at the end of the 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, hives on the skin.

2. You are pregnant

- PHARMACOR MYCOPHENOLATE 250 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 250 during pregnancy.

- You must tell your doctor if you are pregnant or plan to become pregnant.
- 3. You are breastfeeding**
- PHARMACOR MYCOPHENOLATE 250 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 250 therapy, during therapy and for at least six weeks after stopping PHARMACOR MYCOPHENOLATE 250, 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 whether you should start taking this medicine, talk to your doctor.

Before you start to take PHARMACOR MYCOPHENOLATE 250

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 250.
 - 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 250 and for 90 days after you have stopped receiving PHARMACOR MYCOPHENOLATE 250.
 - you should not donate semen while you are being treated with PHARMACOR MYCOPHENOLATE 250 and for 90 days after you have stopped receiving PHARMACOR MYCOPHENOLATE 250.
- 4. You should not donate blood while you are being treated with PHARMACOR MYCOPHENOLATE 250 and for at least 6 weeks after you**

stop receiving PHARMACOR MYCOPHENOLATE 250

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 ulceration or bleeding).
 - rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley- Seegmiller syndrome.
 - kidney disease
 - phenylketonuria.
- 6. 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 250.

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 your pharmacy, supermarket or health food shop.

Some medicines and PHARMACOR MYCOPHENOLATE 250 may interfere with each other. 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.
- acyclovir or 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
- 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 PHARMACOR MYCOPHENOLATE 250, or may affect how well it works. You may need 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 this medicine

How to take PHARMACOR MYCOPHENOLATE 250

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 250 exactly as your doctor has prescribed.

Your doctor will tell you how many PHARMACOR MYCOPHENOLATE 250 capsules to take each day.

PHARMACOR MYCOPHENOLATE 250

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.

How to take it

PHARMACOR MYCOPHENOLATE 250

Swallow the capsules whole with a glass of water.

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

When to take PHARMACOR MYCOPHENOLATE 250

It is best to take doses of PHARMACOR MYCOPHENOLATE 250 mg capsules approximately 12 hours apart.

Take your medicine at about the same time each day.

Taking PHARMACOR MYCOPHENOLATE 250 mg capsules 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 PHARMACOR MYCOPHENOLATE 250

PHARMACOR MYCOPHENOLATE 250 should be taken every day. It is important to keep taking mycophenolate mofetil to ensure your new transplant keeps working properly.

Continue taking PHARMACOR MYCOPHENOLATE 250 for as long as your doctor tells you.

If you forget to take PHARMACOR MYCOPHENOLATE 250

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 medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much PHARMACOR MYCOPHENOLATE 250. 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 250

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 250.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking PHARMACOR MYCOPHENOLATE 250.

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 250.

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 250 therapy, during therapy and for at least six weeks after stopping PHARMACOR MYCOPHENOLATE 250, 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 250 and for 90 days after you have stopped receiving PHARMACOR MYCOPHENOLATE 250.

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

Do not use PHARMACOR MYCOPHENOLATE 250 to treat any other complaints unless your doctors tells you to.

Do not give PHARMACOR MYCOPHENOLATE 250 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 or open PHARMACOR MYCOPHENOLATE 250 capsules.

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 250 affects you or if you experience somnolence, confusion, dizziness, tremor or hypotension. PHARMACOR MYCOPHENOLATE 250 can 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 250.

This medicine 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 receiving PHARMACOR MYCOPHENOLATE 250 therefore develop more infections than usual and this could increase the severity of the infections.

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.

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 or pharmacist 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 250.

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 or feet, lymph nodes
- Hypersensitivity
- breathing difficulties, pain in the chest, chronic cough with blood.

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

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

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

After using PHARMACOR MYCOPHENOLATE 250

Storage

PHARMACOR MYCOPHENOLATE 250

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

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

Keep PHARMACOR MYCOPHENOLATE 250 in a cool dry place where the temperature stays below 25°C.

Do not store PHARMACOR MYCOPHENOLATE 250 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 mycophenolate mofetil where children cannot reach it.

A locked cupboard at least one and a-half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking mycophenolate mofetil; or the capsules have passed their expiry date, ask your pharmacist what to do with any that is left over.

Product description

Availability

PHARMACOR MYCOPHENOLATE 250 come in packs of 100 capsules.

What PHARMACOR MYCOPHENOLATE 250 look like

PHARMACOR MYCOPHENOLATE 250 are oblong, size “1” blue colored cap, brown colored body hard gelatin capsule imprinted with “266” on body with black ink.

Ingredients

Active ingredient:

Each capsule contains 250 mg of mycophenolate mofetil.

Inactive ingredients:

The capsule fill contains:

- Pregelatinised starch
- Croscarmellose sodium
- Povidone
- Magnesium stearate

The capsule shell contains:

- Gelatin
- Sodium lauryl sulphate

The dyes in the capsule shell are:

- Iron oxide red
- Titanium dioxide
- Iron oxide yellow
- FD & C blue 2

PHARMACOR MYCOPHENOLATE 250 is gluten and lactose free.

Manufacturer

PHARMACOR MYCOPHENOLATE 250 is distributed by:

Pharmacor Pty Ltd.

Suite 803, Level 8, Tower A,
The Zenith, 821 Pacific Highway,
Chatswood, NSW 2067,
Australia

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

Australian Registration Numbers

PHARMACOR MYCOPHENOLATE 250
AUST R 173633

DATE OF TGA APPROVAL

21 November 2011

DATE OF MOST RECENT AMENDMENT

05/2022