

MOFIT 500

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 MOFIT 500?

MOFIT 500 contains the active ingredient mycophenolate mofetil. MOFIT 500 is indicated for the prophylaxis of solid organ rejection in adults receiving allogeneic organ transplants and is indicated for the prophylaxis of organ rejection in paediatric patients (2 to 18 years) receiving allogeneic renal transplants.

For more information, see Section [1. Why am I using MOFIT 500?](#) in the full CMI.

2. What should I know before I use MOFIT 500?

Do not use if you have ever had an allergic reaction to MOFIT 500 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 MOFIT 500?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOFIT 500 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 MOFIT 500?

- The dose of MOFIT 500 is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.
- Take MOFIT 500 every day, at about the same time each day with full glass of water.

More instructions can be found in Section [4. How do I use MOFIT 500?](#) in the full CMI.

5. What should I know while using MOFIT 500?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MOFIT 500.• Keep all of your doctor's appointments so that your progress can be checked.• Your doctor will do regular tests (blood, urine or Magnetic Resonance Imaging (MRI)) to make sure the medicine is working and to prevent unwanted side effects.• Your doctor will also use these tests to decide when you should stop taking MOFIT 500.
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 MOFIT 500 affects you.• If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.
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 your medicine in the original container until it is time to take it.• Store it in a cool, dry place, below 30°C.

For more information, see Section [5. What should I know while using MOFIT 500?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: nausea, diarrhoea, vomiting, pain in the abdomen, bloating, constipation or indigestion, rash, headache, itching, swelling of arms or legs, change in the colour of the skin, anxiety, trouble sleeping, tiredness etc. Serious side effects: allergic reaction, severe skin reaction, kidney problem, liver problems, ulcers, gallstones etc.

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.

MOFIT 500

Active ingredient(s): *Mycophenolate mofetil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOFIT 500. **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 MOFIT 500.**

Where to find information in this leaflet:

- [1. Why am I using MOFIT 500?](#)
- [2. What should I know before I use MOFIT 500 ?](#)
- [3. What if I am using other medicines?](#)
- [4. How do I use MOFIT 500?](#)
- [5. What should I know while using MOFIT 500?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MOFIT 500?

MOFIT 500 contains the active ingredient mycophenolate mofetil.

MOFIT 500 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.

MOFIT 500 may be taken together with other medicines known as ciclosporin and corticosteroids.

2. What should I know before I use MOFIT 500?

Warnings

Do not take MOFIT 500 if

- **you are allergic to mycophenolate mofetil, or 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.
- **you are pregnant**
 - MOFIT 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 MOFIT 500 during pregnancy.
 - You must tell your doctor if you are pregnant or plan to become pregnant.

- **you are breastfeeding**
 - MOFIT 500 may pass into human breast milk and could cause serious side effects in your baby if you breastfeed.
- **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 MOFIT 500 therapy, and for at least six weeks after stopping MOFIT 500, unless you are not sexually active.
- **the package is torn or shows signs of tampering**
- **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.

Check with 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 MOFIT 500 and for 90 days after you have stopped receiving MOFIT 500.
 - you should not donate semen while you are being treated with MOFIT 500 and for 90 days after you have stopped receiving MOFIT 500.
- **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
 - have allergies to any other medicines, foods, preservatives or dyes.

You should not donate blood while you are being treated with MOFIT 500 and for at least 6 weeks after you stop receiving MOFIT 500.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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 MOFIT 500.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with MOFIT 500 and affect how it works. These include:

- azathioprine, tacrolimus and sirolimus - medicines used to suppress the immune system which can be used to prevent organ rejection after a transplant
- acyclovir, ganciclovir, valaciclovir or valganciclovir used to treat certain viral infections
- isavuconazole - used to treat fungal infections
- antacids - used to treat heartburn and indigestion
- cholestyramine - used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin-used to treat infections
- iron supplements - 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 such as lansoprazole and Pantoprazole - used to treat indigestion and stomach ulcers
- calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood

These medicines may be affected by MOFIT 500 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 this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MOFIT 500.

4. How do I use MOFIT 500?

How much to take

Take MOFIT 500 exactly as your doctor has prescribed.

Your doctor will tell you how many MOFIT 500 tablets to take each day.

The dose to prevent organ rejection is usually 1g 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.

When to take MOFIT 500

It is best to take doses of MOFIT 500 approximately 12 hours apart.

Taking MOFIT 500 at the same time each day will have the best effect. It will also help you remember when to take it.

How to take MOFIT 500

- Swallow the tablets whole with a full glass of water.
- Do not crush tablets or open or crush capsules. If a capsule breaks open accidentally, wash any powder off your skin with soap and water.

How long to take MOFIT 500

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

Continue taking MOFIT 500 for as long as your doctor tells you.

If you forget to use MOFIT 500

MOFIT 500 should be used regularly at the same time each day.

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 take a double dose to make up for the dose 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 MOFIT 500

If you think that you have taken too much MOFIT 500 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 MOFIT 500?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking MOFIT 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 MOFIT 500. If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning MOFIT 500 therapy, during therapy and for at least six weeks after stopping MOFIT 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 MOFIT 500 and for 90 days after you have stopped receiving MOFIT 500.

Call your doctor straight away if you:

- 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 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 MOFIT 500 or change the dose without first checking with your doctor.
- Do not use MOFIT 500 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 crush MOFIT 500.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

Be careful before you drive or use any machinery or tool until you know how MOFIT 500 affects you

MOFIT 500 may cause affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

MOFIT 500 may affect your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.
- Store below 25°C. Protected from light.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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?

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.

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 MOFIT 500 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 increased chance of side effects occurring due to immunosuppression.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">diarrhoea, constipation, nausea (feeling sick), vomiting or indigestionstomach, chest or back painheadacheurinary infections	Speak to your doctor if you have any of these less serious side effects 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 bleedingsigns of anaemia such as excessive tiredness, dizziness or looking paleswelling of the hands, ankles or feet, lymph nodes (glands)hypersensitivity (skin rash, itching, swelling of the face, lips, throat, or tongue)breathing difficulties, pain in the chest, chronic cough with blood.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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. Other side effects may occur in some people and there may be some others that are not yet known.

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 MOFIT 500 contains

Active ingredient (main ingredient)	Mycophenolate mofetil
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">croscarmellose sodiumpovidonemicrocrystalline cellulose (avicel 102)magnesium stearateinstacoat ICG-U-10130 GREY
Potential allergens	No

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

What MOFIT 500 looks like

MOFIT 500: Lavender coloured caplet shaped biconvex film coated tablets debossed with '265' on one side and plain on other side.

MOFIT 500 available in a PVC/PVDC-Al blister pack of 10's, 30's, 50's, 100's, 150's, and 300's Tablets.

Australian Register Number:

MOFIT 500: 363771

Who distributes MOFIT 500

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia

This leaflet was prepared in 03/2024.