

MYCOPHENOLATE ACCORD

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 Mycophenolate Accord?

Mycophenolate Accord contains the active ingredient mycophenolate mofetil. Mycophenolate Accord is used to prevent the rejection of a transplanted organ.

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

2. What should I know before I use Mycophenolate Accord?

Do not use if you have ever had an allergic reaction to mycophenolate mofetil a related medicine called mycophenolic acid, or any of the ingredients listed at the end of the CMI. Do not use if you are pregnant or breast feeding, or if you are a woman who could become pregnant and you are not using two reliable forms of contraception.

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 Mycophenolate Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mycophenolate Accord 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 Mycophenolate Accord?

Mycophenolate Accord is an injection for infusion and will be given to you by your doctor or nurse.

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

5. What should I know while using Mycophenolate Accord?

Things you should do	Tell any doctor, surgeon, anaesthetist, dentist or pharmacist that is treating you that you are using Mycophenolate Accord. Wear protective clothing and broad-spectrum sunscreen when outdoors.
Things you should not do	Do not stop using this medicine without first checking with your doctor. 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 driving or operating machinery until you know how Mycophenolate Accord affects you, or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

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

6. Are there any side effects?

More common side effects include diarrhoea, constipation, nausea, vomiting, indigestion, pain in the stomach, chest or back, headache, and urinary infection. Less common but possibly serious side effects include infections, bruising, anaemia, swelling of the hands, ankles or lymph nodes (glands), chronic cough with blood and allergic reactions such as chest tightness, wheezing, difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat with difficulty breathing, skin rash, itching or hives (raised red patches of skin that are often very itchy).

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.

MYCOPHENOLATE ACCORD

Active ingredient: *mycophenolate mofetil*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Mycophenolate Accord?

Mycophenolate Accord contains the active ingredient mycophenolate mofetil. Mycophenolate mofetil belongs to a group of medicines called immunosuppressants.

Mycophenolate Accord is 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.

Mycophenolate Accord may be used together with other medicines known as ciclosporin and corticosteroids.

2. What should I know before I use Mycophenolate Accord?

Warnings

Do not use Mycophenolate Accord if:

- you are allergic to mycophenolate mofetil, a related medicine called mycophenolic acid, or any of the other ingredients listed at the end of this leaflet. Some of the symptoms of a serious allergic reaction may include:**
 - chest tightness, wheezing or difficulty breathing
 - severe dizziness or light-headedness
 - swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
 - skin rash, itching or hives (raised red patches of skin that are often very itchy)

Mycophenolate Accord solution should not be given if you have an allergy to polysorbate 80.

- You are pregnant**

- Mycophenolate Accord 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 Mycophenolate Accord during pregnancy.
- You must tell your doctor if you are pregnant or plan to become pregnant.
- **You are breast feeding**
 - Mycophenolate Accord can 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 Mycophenolate Accord therapy, during therapy, and for at least six weeks after stopping Mycophenolate Accord, unless you are not sexually active.

If you are not sure whether you should start using 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 Mycophenolate Accord and for 90 days after you have stopped receiving Mycophenolate Accord
 - you should not donate semen while you are being treated with Mycophenolate Accord and for 90 days after you have stopped receiving Mycophenolate Accord
- **have any other health problems, especially the following:**
 - a history of sunspots 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 Mycophenolate mofetil and for at least 6 weeks after you stop receiving Mycophenolate Accord.

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 Mycophenolate Accord.

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 Mycophenolate Accord 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
- aciclovir, 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, medicines 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
- telmisartan - used to treat high blood pressure
- calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood

These medicines may be affected by Mycophenolate Accord 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 Mycophenolate Accord.

4. How do I use Mycophenolate Accord?

How much to use

Mycophenolate Accord is given to you as an infusion into your vein (intravenously), usually over a period of two or more hours. It is only given in a hospital setting and doses are usually 12 hours apart.

Your doctor will decide what dose of Mycophenolate Accord you will be given. The infusion dose to prevent organ rejection is usually 2 g to 3 g per day depending on which organ has been transplanted.

Your doctor may adjust the dose during treatment depending on your response.

When to use Mycophenolate Accord

If you are receiving Mycophenolate Accord infusion, your doctor will most likely change this medication to mycophenolate mofetil capsules, tablets or suspension once you are able to take these.

If you use too much Mycophenolate Accord

It is unlikely that you will receive an overdose of Mycophenolate Accord because a trained nurse or doctor will give it. If you think that you have been given too much Mycophenolate Accord, 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 Mycophenolate Accord?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are using Mycophenolate Accord

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

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

Do not use Mycophenolate Accord to treat any other complaints unless your doctor tells you to.

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 driving or operating machinery until you know how Mycophenolate Accord affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

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

Looking after your medicine

The hospital will store Mycophenolate Accord under the correct conditions.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any Mycophenolate Accord that may be left over.

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.

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 Mycophenolate Accord 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.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious 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, muscle or back pain • headache • urinary infections • acne • hair loss or itchy skin 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects (rare)	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 (glands) • inability to sleep (insomnia) • signs of allergic reaction (chest tightness, wheezing or difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing, skin rash, itching or hives appearing as raised red patches of skin that are often very itchy) • breathing difficulties, pain in the chest, chronic cough with blood. 	<p>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.</p>

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 is 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 Mycophenolate Accord contains

Active ingredient (main ingredient)	mycophenolate mofetil
Other ingredients (inactive ingredients)	citric acid hydrochloric acid polysorbate 80 sodium chloride sodium hydroxide

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

What Mycophenolate Accord looks like

Mycophenolate Accord infusion is a sterile white to off-white powder in a clear glass vial. It will be made up into an infusion bag before being given to you. (500 mg Aust R 327728).

Who distributes Mycophenolate Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

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