

Mycophenolate AN

Mycophenolate Mofetil 500 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mycophenolate AN.

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 Mycophenolate AN 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 Mycophenolate AN is used for

Mycophenolate AN contains the active ingredient mycophenolate mofetil.

Mycophenolate AN 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.

Mycophenolate AN belongs to a new group of these medicines.

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

Your doctor, however, may have prescribed Mycophenolate AN for another purpose.

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

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

Mycophenolate AN is not addictive.

Before you take Mycophenolate AN

When you must not take it

Do not take Mycophenolate AN if:

- You have had an allergic reaction to Mycophenolate AN 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
- You are pregnant.**
Mycophenolate AN 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 AN during pregnancy.
You must tell your doctor if you are pregnant or plan to become pregnant.
- You are breastfeeding.**
Mycophenolate AN 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 Mycophenolate AN therapy, during therapy and for at least six weeks after stopping Mycophenolate AN, 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 if you should be taking Mycophenolate AN, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 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 Mycophenolate AN.
Repeat pregnancy tests will be performed during routine follow-up visits with your doctor.
- You are breast-feeding or plan to breast-feed.**
- 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 AN and for 90 days after you have stopped receiving Mycophenolate AN.
- 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
- 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 Mycophenolate AN.

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 Mycophenolate AN. These medicines include:

- aciclovir or ganciclovir, valaciclovir or valganciclovir, medicines used to treat viral infections

- antacids, medicines used to treat heartburn and indigestion
- azathioprine, a medicine used to suppress the immune system
- calcium-free phosphate binders (such as sevelamer), medicines used to treat high phosphate 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
- cholestyramine, a medicine used to treat high cholesterol levels in the blood
- iron supplements, medicines used to treat low iron levels in the blood
- norfloxacin plus metronidazole, and amoxicillin plus clavulanic acid, combination of antibiotics used to treat infections
- rifampicin and ciprofloxacin, medicines used to treat infections
- tacrolimus, a medicine used to suppress the immune system
- sirolimus, a medicine used to prevent organ rejection after a transplant

These medicines may be affected by Mycophenolate AN, 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 Mycophenolate AN.

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

How to take Mycophenolate AN

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 Mycophenolate AN exactly as your doctor has prescribed.

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

Mycophenolate AN

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.

Mycophenolate AN 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 Mycophenolate AN 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

Mycophenolate AN

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 Mycophenolate AN.

How long to take Mycophenolate AN

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

Continue taking Mycophenolate AN until your doctor tells you to stop.

If you forget to take Mycophenolate AN

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 Mycophenolate AN. 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 Mycophenolate AN

Things you must do

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

Tell your doctor if you become pregnant while taking Mycophenolate AN.

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

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

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Mycophenolate AN to anyone else even if they have the same condition as you.

Do not use Mycophenolate AN to treat other complaints unless your doctor says so.

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 Mycophenolate AN affects you.

However, Mycophenolate AN 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 Mycophenolate AN.

Mycophenolate AN helps most people who have 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 Mycophenolate AN 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.

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
- fluid in the legs or arms
- urinary infections

These are the more common side effects of Mycophenolate AN. 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
- Unexpected bruising or bleeding
- Clumsiness
- Weakness
- Changes in vision or speech
- Signs of anaemia such as excessiveness tiredness, dizziness or looking pale

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 Mycophenolate AN

Storage

Mycophenolate AN

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 Mycophenolate AN 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 Mycophenolate AN to fade.

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

Product description

Availability

Mycophenolate AN is available in blister packs of 50 tablets.

What Mycophenolate AN looks like

Mycophenolate AN 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
carmin (CI73015) and Iron oxide black
(CI77499)

Mycophenolate AN is gluten and lactose free.

Australian Registration Number

Mycophenolate AN:
AUST R 164416

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd
12 River Street
Melbourne Victoria 3141
Australia

Date of Preparation

March 2016