

Mycophenolate APOTEX

mycophenolate mofetil

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

This medicine contains the active ingredient mycophenolate mofetil.

Mycophenolate 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.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine for children under the age of 6 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing mycophenolate mofetil
- 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

Do not take this medicine if you are pregnant or plan to become pregnant.

Mycophenolate 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 during pregnancy.

You must tell your doctor if you are pregnant or plan to become pregnant.

In addition, if you are a woman of child-bearing potential, then you must use two reliable forms of contraception at the same time before beginning mycophenolate therapy, during therapy, and for at least six weeks after stopping mycophenolate, unless you are not sexually active.

Do not breastfeed if you are taking this medicine.

Mycophenolate may pass into human breast milk and could cause serious side effects in your baby if you breastfeed.

Do not donate blood while you are being treated, and for at least 6 weeks after you stop receiving treatment with this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding, or you are a sexually active male.

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.

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

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 and for 90 days after you have stopped receiving mycophenolate.

You should not donate semen while you are being treated with mycophenolate and for 90 days after you have stopped receiving mycophenolate.

Tell your doctor if you have or have had any of the following medical conditions:

- 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

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and this one may interfere with each other. These include:

- acyclovir, ganciclovir, valaciclovir or valganciclovir, medicines used to treat viral infections
- antacids or proton-pump inhibitors (such as pantoprazole or lansoprazole), medicines used to treat heartburn, indigestion or stomach ulcers
- azathioprine, tacrolimus or sirolimus, 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
- cholestyramine, 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
- telmisartan, used to lower blood pressure
- isavuconazole, used to treat fungal infections

These medicines may be affected by mycophenolate 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.

How to take this medicine

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 directions, ask your doctor or pharmacist for help.

How much to take

Take this medicine exactly as your doctor has prescribed.

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

Adults

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.

Children (6-18 years old)

Mycophenolate is not suitable for paediatric patients whose body surface area is less than 1.50 m².

Patients with a body surface area greater than 1.50 m² may be dosed with 1 g twice daily (2 g daily dose).

Your doctor may adjust your dose depending on your response.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush the tablets.

When to take it

Take your medicine at about the same time each day. Take each dose approximately 12 hours apart.

Taking it 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 it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

Stop using this medicine when the redness and itching have gone.

If you forget to take it

If it is almost time to take 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 your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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 take this medicine 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 stop taking your medicine or change the dosage without checking with your doctor.

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 this medicine affects you.

However, mycophenolate 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 this medicine.

This medicine helps most people who have had 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 attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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 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.

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, back or other pain
- headache
- fluid in the legs or arms
- urinary infections

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 excessive tiredness, dizziness or looking pale
- swelling of the hands, ankles, feet or lymph nodes
- hypersensitivity
- breathing difficulties, pain in the chest or chronic cough with blood
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people and there may be some others that are not yet known.

Storage and Disposal

Storage

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 your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Always keep the tablets away from direct light. Light will cause the tablets to fade.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Mycophenolate APOTEX looks like

Purple coloured, capsule shaped, biconvex, film coated tablets debossed 'AHI' on one side and '500' on other side. AUST R 235572.

Available in blister packs of 50 tablets.

Ingredients

This medicine contains 500 mg of mycophenolate mofetil as the active ingredient.

This medicine also contains the following:

- microcrystalline cellulose
- povidone
- hypromellose
- croscarmellose sodium
- purified talc
- magnesium stearate
- Opadry complete film coating system 03B50110 PURPLE, which includes hypromellose, titanium dioxide, macrogol 400, iron oxide red, indigo carmine and iron oxide black.

This medicine does not contain lactose or gluten.

Distributor

This medicine is distributed in
Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

This leaflet was last updated in
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