APO-Mycophenolate Tablets

Contains the active ingredient 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 mycophenolate mofetil.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Mycophenolate. It contains the active ingredient mycophenolate mofetil.

It is used for:

- the prophylaxis of solid organ rejection in adults receiving allogeneic organ transplants
- the prophylaxis of organ rejection in paediatric patients (2 to 18 years) receiving allogeneic renal transplants.

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

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

How it works

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

There is no evidence that this medicine is addictive.

Use in children

Do not give mycophenolate mofetil to children under the age of 2 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to mycophenolate mofetil or any of the ingredients listed at the end of this leaflet.**

  Symptoms of an allergic reaction may include 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; fainting or hayfever-like symptoms.

  If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You are currently pregnant or you plan to become pregnant.

   It is not known whether mycophenolate mofetil is harmful to the unborn baby when taken during pregnancy. There have been cases of birth defects reported in patients exposed to mycophenolate mofetil in combination with other immunosuppressants during pregnancy.

   Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

   Female patients of childbearing potential must use effective contraception before, during and for six weeks after receiving mycophenolate mofetil.

3. You are currently breast-feeding or you plan to breast-feed.

   It is not known if mycophenolate mofetil passes into breast milk. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

4. You have or have had any medical conditions, especially the following:

- sun spots or skin cancers
- low blood counts for neutrophils (a type of white blood cell)
- serious stomach or bowel problems (such as ulcers or bleeding)
- kidney disease
- rare hereditary deficiency of an enzyme called hypoxanthine-guanine phosphoribosyltransferase (HGPRT), such as Lesch-Nyhan and Kelley-Seegmiller syndrome.

5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with mycophenolate mofetil. These include:

- aciclovir and ganciclovir, 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, medicines that work by causing your body to produce its own protection against an infectious disease
- 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 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with mycophenolate mofetil.

Your doctor or pharmacist has 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.

Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Take this medicine exactly as your doctor has prescribed.

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

For renal transplant only.

For children 2 to 18 years of age, the dose to prevent rejection is dependent on your child's height and weight. The maximum dose is usually 1 g in the morning and 1 g at night (maximum 2 g daily).

Your doctor may adjust your dose depending on your response.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow mycophenolate mofetil 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.

Take your medicine at the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take your medicine.

How long to take it for

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

It is important to keep taking mycophenolate mofetil to ensure your new transplant keeps working properly.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant

  Female patients of childbearing potential must use effective contraception before, during and for six weeks after receiving mycophenolate mofetil.
- you are breast-feeding or are planning to breastfeed
- you are going to have surgery or an anaesthetic or are going into hospital.
- you plan to have any vaccinations or immunisations
- you are about to have any blood tests.

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.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

To stop you rejecting your organ transplant, mycophenolate mofetil reduces your body's own defence mechanisms. This means your body will not be as good at fighting infection. People taking mycophenolate mofetil, therefore develop more infections than usual.

Patients who receive immunosuppressant medicines such as mycophenolate mofetil, 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 to answer any questions you may have.

Tell your doctor if you notice any of the following:

- diarrhoea, constipation, nausea (feeling sick) 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 mofetil. Mostly these are mild.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department 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.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

These are not complete lists of all possible side effects. Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on these lists.

Allergic reactions

If you think you are having an allergic reaction to mycophenolate mofetil, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C and protect from light.

Do not store your 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Mycophenolate looks like

APO-Mycophenolate 500 mg is a lavender coloured, capsule shaped, film coated tablets, engraved with 'APO' and 'MYC500' on the other.

Ingredients

Each APO-Mycophenolate tablets contains 500 mg of mycophenolate mofetil as the active ingredient.

It also contains the following inactive ingredients:

- cellulose - microcrystalline
- croscarmellose sodium
- silica - colloidal anhydrous
- magnesium stearate
- Opadry Film-Coating System 20B50135 Purple

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

APO-Mycophenolate is available in blister packs of 50 and 150 tablets and bottles of 50, 150 and 500 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Australian Registration Numbers

APO-Mycophenolate 500 mg tablets (blister pack): AUST R 168111

APO-Mycophenolate 500 mg tablets (bottle): AUST R 168105

Sponsor

Apotex Pty Ltd

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Australia

This leaflet was prepared in April 2012.