

# **APO-Mycophenolate Capsules**

Contains the active ingredient mycophenolate mofetil

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

**Read this leaflet carefully before taking your medicine.**

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 pregnant.**

Mycophenolate mofetil 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 mofetil during

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

- **You are breastfeeding.**

Mycophenolate mofetil 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 mofetil therapy, during therapy and for at least six weeks after stopping mycophenolate mofetil, unless you are not sexually active.

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

**3. You are currently pregnant, or you plan to become pregnant.**

Do not take this medicine whilst pregnant. You must have two negative pregnancy tests 8-10 days apart just prior to starting treatment with mycophenolate mofetil.

**4. You are currently breastfeeding, or you plan to breastfeed.**

Do not take this medicine whilst breastfeeding.

- 5. You should not donate blood while you are being treated and for at least 6 weeks after you stop receiving treatment with mycophenolate mofetil**
- 6. 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.
- 7. You have recently been vaccinated or plan to get a vaccination.**
- 8. You are planning to have surgery or an anaesthetic.**
- 9. You are currently receiving or are planning to receive dental treatment.**
- 10. 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 and proton-pump inhibitors (PPIs), medicines used to treat heartburn and indigestion
- azathioprine, tacrolimus and sirolimus, medicines used to suppress the immune system which can be used to prevent organ rejection after a transplant
- 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
- amoxicillin plus clavulanic acid, norfloxacin plus metronidazole, rifampicin and ciprofloxacin, antibiotics used to treat infections
- telmisartan, a medication used to lower blood pressure

- isavuconazole, a medicine used to treat fungal infections

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 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 capsules whole, with a glass of water.

**If a capsule breaks open accidentally, wash off any powder thoroughly with soap and 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 planning to become pregnant
- you are breastfeeding 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.

## **Tell your doctor if you become pregnant while taking this medicine.**

If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning mycophenolate mofetil therapy, during therapy and for at least six weeks after stopping mycophenolate mofetil, 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

mofetil and for 90 days after you have stopped receiving mycophenolate mofetil.

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

**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.

**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.

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 or if you experience somnolence, confusion, dizziness, tremor or hypotension.**

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

## **Possible side effects**

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

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.**

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.

**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
- changes in vision or speech
- signs of anaemia such as excessive tiredness, dizziness or looking pale
- swelling of the hands, ankles or feet, lymph nodes
- hypersensitivity
- breathing difficulties, pain in the chest, chronic cough with blood

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 250 mg is a hard gelatine, size 1, capsule containing white to off-white powder with an opaque blue cap and an opaque pink body with 'APO' and 'M250' imprinted in black ink.

Blister pack of 100 or 300 capsules and bottles of 100, 300 and 500 capsules.

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

## **Ingredients**

Each APO-Mycophenolate capsules contains 250 mg of mycophenolate mofetil as the active ingredient.

It also contains the following inactive ingredients:

- croscarmellose sodium
- magnesium stearate
- gelatin

- indigo carmine
- iron oxide red
- titanium dioxide
- sodium lauryl sulfate
- black printing ink (TEK SW 9008)
- purified water

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

## **Australian Registration Numbers**

APO-Mycophenolate 250 mg capsules (blister pack):

AUST R 168109

APO-Mycophenolate 250 mg capsules (bottle): AUST R 168108

## **Sponsor**

Apotex Pty Ltd

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Australia

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