

# APO-Mycophenolate

## 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 APO-Mycophenolate?

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

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

### 2. What should I know before I use APO-Mycophenolate?

Do not use if you have ever had an allergic reaction to mycophenolate mofetil 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 APO-Mycophenolate?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-Mycophenolate 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 APO-Mycophenolate?

- Your doctor will tell you how many APO-Mycophenolate capsules to take each day  
More instructions can be found in Section [4. How do I use APO-Mycophenolate?](#) in the full CMI.

### 5. What should I know while using APO-Mycophenolate?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist that is treating you that you are using APO-Mycophenolate.</li><li>Wear protective clothing and broad-spectrum sunscreen when outdoors.</li></ul>  |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>Do not stop using this medicine without first checking with your doctor.</li><li>Do not take any other medicines - whether they require a prescription or not - without first telling your doctor or consulting with a pharmacist</li></ul> |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how APO-Mycophenolate affects you, or if you experience somnolence (drowsiness) (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).</li></ul>          |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"><li>n/a</li></ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>Keep APO-Mycophenolate capsules in a cool dry place where the temperature stays below 25°C.</li></ul>   |

For more information, see Section [5. What should I know while using APO-Mycophenolate?](#) 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), hypersensitivity (skin rash, itching, swelling of the face, lips, throat, or tongue), breathing difficulties, pain in the chest, and chronic cough with blood

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.

# APO-Mycophenolate

Active ingredient(s): *Mycophenolate mofetil*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using APO-Mycophenolate?

**APO-Mycophenolate contains the active ingredient Mycophenolate mofetil.** APO-Mycophenolate is an immunosuppressant. Immunosuppressants are 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.

APO-Mycophenolate may be taken together with other medicines known as ciclosporin and corticosteroids.

## 2. What should I know before I use APO-Mycophenolate?

### Warnings

**Do not use APO-Mycophenolate if:**

- you are allergic to mycophenolate mofetil, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - shortness of breath, chest tightness
  - wheezing or difficulty breathing
  - severe dizziness or light headedness
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine.
- **You are pregnant.**

APO-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 APO-Mycophenolate during pregnancy.
- You must tell your doctor if you are pregnant or plan to become pregnant.
- **you are breast feeding**
  - APO-Mycophenolate 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 APO-Mycophenolate therapy, during therapy, and for at least six weeks after stopping APO-Mycophenolate, 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 whether you should start taking 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 APO-Mycophenolate and for 90 days after you have stopped receiving APO-Mycophenolate
  - you should not donate semen while you are being treated with APO-Mycophenolate and for 90 days after you have stopped receiving APO-Mycophenolate
- **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 ulceration or bleeding)
  - rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
  - kidney disease
  - phenylketonuria. You may not be able to take APO-Mycophenolate oral suspension as it is a source of phenylalanine.
  - have allergies to any other medicines, foods, preservatives or dyes.

- **You should not donate blood while you are being treated with APO-Mycophenolate and for at least 6 weeks after you stop receiving APO-Mycophenolate.**

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 APO-Mycophenolate.

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

### **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 APO-Mycophenolate 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
- acyclovir, 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 - 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
- calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood

These medicines may be affected by APO-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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Mycophenolate.**

### **4. How do I use APO-Mycophenolate?**

#### **How much to take / use**

Follow the instructions provided and use APO-Mycophenolate exactly as your doctor prescribed. Your doctor will tell you how many APO-Mycophenolate capsules to take each day

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.

Swallow the capsules whole with a full glass of water. Do not open or crush capsules. If a capsule breaks open accidentally, wash any powder off your skin with soap and water.

#### **When to take APO-Mycophenolate**

It is best to take doses of APO-Mycophenolate capsules, approximately 12 hours apart. Taking APO-Mycophenolate 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 APO-Mycophenolate**

APO-Mycophenolate should be taken every day. It is important to keep taking APO-Mycophenolate to ensure your new transplant keeps working properly. Continue taking APO-Mycophenolate for as long as your doctor tells you.

#### **If you forget to use APO-Mycophenolate**

APO-Mycophenolate should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

**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 use too much APO-Mycophenolate**

If you think that you have used too much APO-Mycophenolate, 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 APO-Mycophenolate?

### Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking APO-Mycophenolate.

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

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 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 APO-Mycophenolate or change the dose without first checking with your doctor.
- Do not use APO-Mycophenolate 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 let yourself run out of medicine over the weekend or on holidays.
- Do not crush or open APO-Mycophenolate capsules.
- 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 before you drive or use any machines or tools until you know how APO-Mycophenolate affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Keep your capsules in the blister pack until it is time to take them. If you take the capsules out of the blister pack they may not keep well.
- Keep APO-Mycophenolate capsules in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine (as relevant)

Do not use this medicine after the expiry date.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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 receiving APO-Mycophenolate 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 increased chance of side effects occurring due to immunosuppression.

## Less serious side effects

| Less serious side effects  | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>• diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion</li><li>• stomach, chest or back pain</li><li>• headache</li><li>• urinary infections</li><li>• Acne</li><li>• hair loss or itchy skin</li></ul> | Speak to your doctor if you have any of these less serious side effects and they worry you. |

## Serious side effects

| Serious side effects   | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>• signs of other infections, e.g. fevers, chills, sore throat, ulcers of the mouth, abdominal pain or bloody stools.</li><li>• unexpected bruising or bleeding</li><li>• signs of anaemia such as excessive tiredness, dizziness or looking pale</li><li>• swelling of the hands, ankles or feet, lymph nodes (glands)</li><li>• 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)</li><li>• breathing difficulties, pain in the chest, chronic cough with blood.</li></ul> | <b>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.</b> |

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 may be 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](http://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 APO-Mycophenolate contains

|   |   |
|---|---|
| <b>Active ingredient (main ingredient)</b>      | Mycophenolate mofetil   |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• croscarmellose sodium</li><li>• magnesium stearate</li><li>• gelatin</li><li>• indigo carmine</li><li>• iron oxide red</li><li>• titanium dioxide</li><li>• sodium lauryl sulfate</li><li>• black printing ink (TEK SW 9008)</li><li>• purified water</li></ul> |
| <b>Potential allergens</b>                      | capsules are gluten and lactose free.   |

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

### 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 (AUST R 168109)

Bottles of 100, 300 and 500 capsules. (AUST R 168108\*)

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

### Who distributes APO-Mycophenolate

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

Australia

Ph: 1800 195 055

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