

# MYCOPHENOLATE GH

(mycophenolate mofetil) film-coated tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about mycophenolate.

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 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 GH is used for

Mycophenolate GH 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.

There are many different types of medicines used to prevent transplant rejection.

Mycophenolate belongs to a new group of these medicines.

Mycophenolate may be used together with other medicines

known as ciclosporins and corticosteroids.

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

**Ask your doctor if you have any questions about why mycophenolate has been prescribed for you.**

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

Mycophenolate GH is not addictive.

### Before you take Mycophenolate GH

*When you must not take it*

**Do not take this medicine if:**

- 1. You have had an allergic reaction to it 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.

- 2. You are 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.

- 3. You are breastfeeding.**

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

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

- 5. The package is torn or shows signs of tampering.**
- 6. 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 GH, talk to your doctor.**

*Before you start to take it*

**Tell your doctor if:**

- 1. 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.

Repeat pregnancy tests will be performed during routine

follow-up visits with your doctor.

**2. You are breast-feeding or plan to breast-feed.**

**3. 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 GH and for 90 days after you have stopped receiving Mycophenolate GH.

**4. 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.

**5. 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 GH.**

*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 GH. 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 GH, 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 GH.

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

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## How to take Mycophenolate GH

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**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 this medicine exactly as your doctor has prescribed.**

Your doctor will tell you how many tablets, 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.

Mycophenolate is not suitable for paediatric patients whose body surface area is <1.50 m<sup>2</sup>. Patients with a body surface area >1.5 m<sup>2</sup> 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 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 it.

*How long to take it*

This medicine should be taken every day. It is important to keep taking your tablets to ensure your new transplant keeps working properly.

**Continue taking this medicine until your doctor tells you to stop.**

### *If you forget to take it*

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 in Australia or 0800 764 766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much. 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.

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## While you are taking Mycophenolate GH

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### *Things you must do*

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

**Tell your doctor if you become pregnant while taking Mycophenolate GH.**

If you are a woman of child bearing potential, 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 GH and for 90 days after you have stopped receiving Mycophenolate GH.

**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 taking this medicine 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 this medicine to anyone else even if they have the same condition as you.**

**Do not use this medicine to treat other complaints unless your doctor says to.**

**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 GH affects you.**

However, Mycophenolate GH is not expected to affect your ability to drive a car or operate machinery.

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## Side effects

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

Mycophenolate 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 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 GH. 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, eg. 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.

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.**

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## After taking Mycophenolate GH

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### 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 this medicine 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 the tablets to fade.

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

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## Product description

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Mycophenolate GH is available in blister packs of 50 tablets.

### What it looks like

Mycophenolate GH tablets are purple coloured, capsule-shaped, biconvex, film-coated tablets debossed 'AHI' on one side and '500' on other side.

### Ingredients

#### Active Ingredient

Each tablet contains 500 mg mycophenolate mofetil.

#### Inactive Ingredients

- Microcrystalline cellulose
- Povidone
- Hyprollose
- 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.

The tablets are gluten and lactose free.

### Australian Registration Number

Mycophenolate GH: AUST R 318884

### Distributor

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