

Mycophenolate Sandoz®

mycophenolate mofetil capsules and tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mycophenolate Sandoz.

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 want to read it again.

What Mycophenolate Sandoz is used for

This medicine is used to prevent rejection of transplanted organs.

It contains the active ingredient mycophenolate mofetil.

Mycophenolate mofetil belongs to a group of medicines called immunosuppressants.

It works by stopping your immune system from reacting to the transplanted organ.

Mycophenolate Sandoz may be used together with other medicines known 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 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 2 years.

Before you take Mycophenolate Sandoz

When you must not take it

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

- mycophenolate mofetil, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.

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.

Mycophenolate Sandoz 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.

Do not take this medicine if you are breastfeeding.

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

Do not take this medicine if 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.

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.

If you are a woman of childbearing potential, you must have two negative pregnancy tests 8-10 days apart just prior to starting treatment with mycophenolate mofetil.

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

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 Kelley-Seegmiller syndrome
- kidney disease.

If you have not told your doctor about any of the above, tell him/her before you start taking Mycophenolate Sandoz.

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 Mycophenolate Sandoz may interfere with each other. These include:

- aciclovir or ganciclovir, medicines used to treat viral infections
- antacids or proton pump inhibitors (such as lansoprazole and pantoprazole), medicines

used to treat heartburn and indigestion

- tacrolimus or azathioprine, medicines used to suppress the immune system
- sirolimus, a medicine 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, (especially live 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
- ciprofloxacin, rifampicin or norfloxacin plus metronidazole and amoxicillin plus clavulanic acid, medicines used to treat infections.

These medicines may be affected by Mycophenolate Sandoz 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 Mycophenolate Sandoz

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 instructions, ask your doctor or pharmacist for help.

How much to take

Take Mycophenolate Sandoz exactly as your doctor has prescribed.

Your doctor will tell you how many Mycophenolate Sandoz capsules or tablets to take each day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Mycophenolate Sandoz may not work as well and your problem may not improve.

The dose to prevent organ rejection is usually 2g to 3g per day depending on which organ has been transplanted. Half of your daily dose should be taken in the morning, and half should be taken at night.

How to take it

Swallow the tablets/capsules whole with a glass of water.

The tablets should not be crushed and the capsules should not be opened or crushed. Avoid inhalation or any direct contact with powder contained in the capsules or any powder from the tablets. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.

When to take Mycophenolate Sandoz

It is best to take doses approximately 12 hours apart. Your dose can be taken with or without food.

Take your medicine at about the same time each day.

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 Mycophenolate Sandoz

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

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

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Mycophenolate Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Mycophenolate Sandoz

Things you must do

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

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are a woman of childbearing 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.

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

Your doctor will need to give you regular blood tests 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 stop taking your medicine or lower the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take Mycophenolate Sandoz to treat any other complaints unless your doctor tells you 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 Sandoz affects you.

However, Mycophenolate Sandoz 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 Mycophenolate Sandoz.

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.

Mycophenolate Sandoz helps most people who have transplants but it may have unwanted side effects in a few people.

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 this medicine 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.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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 Sandoz. Mostly these are mild.

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.

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

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

Other side effects not listed above may also occur in some people.

After taking Mycophenolate Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Mycophenolate Sandoz 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 Sandoz capsules look like

Mycophenolate Sandoz 250mg - capsules, blue on one end and orange on the other.

Available in blister packs of 100 capsules.

Ingredients

Active ingredients:

- Mycophenolate Sandoz 250mg - 250mg mycophenolate mofetil.

Inactive ingredients:

The capsule fill contains:

- pregelatinised maize starch
- croscarmellose sodium
- povidone
- magnesium stearate.

The capsule shell contains:

- gelatin
- titanium dioxide
- iron oxide red
- iron oxide yellow
- indigo carmine.

What Mycophenolate Sandoz tablets look like

Mycophenolate Sandoz 500mg - lavender coloured, capsule shaped tablets, plain on both sides.

Available in blister packs of 50 tablets.

Ingredients

Active ingredients:

- Mycophenolate Sandoz 500mg - 500mg mycophenolate mofetil.

Inactive ingredients:

- microcrystalline cellulose
- povidone
- talc
- croscarmellose sodium
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- titanium dioxide

- macrogol 400
- iron oxide black
- iron oxide red.

Mycophenolate Sandoz tablets and capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

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- Mycophenolate Sandoz 250mg capsules - AUST R 148227 (blisters)
- Mycophenolate Sandoz 500mg tablets - AUST R 148225 (blisters).