

Mycophenolate Sandoz[®]

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 taking Mycophenolate Sandoz?

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

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

2. What should I know before I take Mycophenolate Sandoz?

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 take Mycophenolate Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mycophenolate Sandoz 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 take Mycophenolate Sandoz?

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

More instructions can be found in Section [4. How do I take Mycophenolate Sandoz?](#) in the full CMI.

5. What should I know while taking Mycophenolate Sandoz?

Things you should do	<ul style="list-style-type: none">Tell any doctor, surgeon, anaesthetist, dentist or pharmacist that is treating you that you are using Mycophenolate Sandoz.Wear protective clothing and broad-spectrum sunscreen when outdoors.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine without first checking with your doctor.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	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Mycophenolate Sandoz affects you, or if you experience somnolence (drowsiness) (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).
Looking after your medicine	<ul style="list-style-type: none">Keep Mycophenolate Sandoz capsules and tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while taking Mycophenolate Sandoz?](#) 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), chronic cough with blood and allergic reactions such as chest tightness, wheezing, difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat with difficulty breathing, skin rash, itching or hives (raised red patches of skin that are often very itchy).

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.

Mycophenolate Sandoz®

Active ingredient(s): *mycophenolate mofetil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mycophenolate Sandoz. **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 Mycophenolate Sandoz.**

Where to find information in this leaflet:

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

1. Why am I taking Mycophenolate Sandoz?

Mycophenolate Sandoz contains the active ingredient **mycophenolate mofetil**. Mycophenolate Sandoz belongs to a group of medicines called immunosuppressants.

Mycophenolate Sandoz is 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.

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

2. What should I know before I take Mycophenolate Sandoz?

Warnings

Do not use Mycophenolate Sandoz if:

- you are allergic to mycophenolate mofetil, a related medicine called mycophenolic acid, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of a serious allergic reaction may include:
 - 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 (raised red patches of skin that are often very itchy).
- 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.
- you are breast feeding**
 - Mycophenolate Sandoz 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 Sandoz therapy, during therapy, and for at least six weeks after stopping Mycophenolate Sandoz, 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 Mycophenolate Sandoz and for 90 days after you have stopped receiving Mycophenolate Sandoz
 - you should not donate semen while you are being treated with Mycophenolate Sandoz and for 90 days after you have stopped receiving Mycophenolate Sandoz
- 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
 - have allergies to any other medicines, foods, preservatives or dyes.

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

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.

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 Sandoz.

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

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

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 Mycophenolate Sandoz 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
- aciclovir, ganciclovir, valaciclovir or valganciclovir used to treat certain viral infections
- isavuconazole - used to treat fungal infections
- antacids - used to treat heartburn and indigestion
- colestyramine - used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin and other medicines 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
- telmisartan - used to treat high blood pressure
- calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood

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.

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

4. How do I take Mycophenolate Sandoz?

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.
- 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.

How to take Mycophenolate Sandoz

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

When to take Mycophenolate Sandoz

- It is best to take doses of Mycophenolate Sandoz capsules or tablets approximately 12 hours apart.
- Taking Mycophenolate Sandoz 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

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

If you forget to take Mycophenolate Sandoz

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 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 take too much Mycophenolate Sandoz

If you think that you have used too much Mycophenolate Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), 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 taking Mycophenolate Sandoz?

Things you should 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 Mycophenolate Sandoz.

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

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 Mycophenolate Sandoz or change the dose without first checking with your doctor.

Do not use Mycophenolate Sandoz 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 Mycophenolate Sandoz tablets or open Mycophenolate Sandoz 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 Mycophenolate Sandoz affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

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

Looking after your medicine

- Keep your capsules or tablets in the blister pack until it is time to take them. If you take the capsules or tablets out of the blister pack they may not keep well.
- Keep Mycophenolate Sandoz capsules and tablets in a cool dry place where the temperature stays below 30°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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

Do not use this medicine after the expiry date.

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 mycophenolate mofetil 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">diarrhoea, constipation, nausea (feeling sick), vomiting or indigestionstomach, chest, muscle or back painheadacheurinary infectionsacnehair loss or itchy skin	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">signs of other infections, e.g. fevers, chills, sore throat, ulcers of the mouth, abdominal pain or bloody stools.unexpected bruising or bleedingsigns of anaemia such as excessive tiredness, dizziness or looking paleswelling of the hands, ankles or feet, lymph nodes (glands)inability to sleep (insomnia)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)breathing difficulties, pain in the chest, chronic cough with blood.	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.

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 or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Mycophenolate Sandoz contains

Mycophenolate Sandoz Capsules

Active ingredient (main ingredient)	mycophenolate mofetil
Other ingredients (inactive ingredients)	<u>Capsule fill:</u> pregelatinised maize starch croscarmellose sodium povidone magnesium stearate. <u>Capsule shell:</u> gelatin titanium dioxide iron oxide red iron oxide yellow indigo carmine.
Potential allergens	Mycophenolate Sandoz capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

Mycophenolate Sandoz Tablets

Active ingredient (main ingredient)	mycophenolate mofetil
Other ingredients (inactive ingredients)	microcrystalline cellulose povidone purified talc croscarmellose sodium magnesium stearate hypromellose hypromellose titanium dioxide macrogol 400 iron oxide black iron oxide red.
Potential allergens	Mycophenolate Sandoz tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What Mycophenolate Sandoz looks like

Mycophenolate Sandoz 250 mg capsules – blue on one end and orange on the other. Available in blister packs of 100 and 300 capsules (Aust R 148227).

Mycophenolate Sandoz 500 mg tablets – lavender coloured, capsule shaped tablets, plain on both sides. Available in blister packs of 50 and 150 tablets (Aust R 148225).

Not all strengths or presentations may be marketed.

Who distributes Mycophenolate Sandoz

Mycophenolate Sandoz is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Mycophenolate Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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