

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 Sandimmun?

Sandimmun contains the active ingredient ciclosporin. Sandimmun is used to prevent organ rejection in people who have had kidney, liver or heart transplant. It is also used to treat different diseases that occur due to issues with your immune system such as nephrotic syndrome (a kidney disease), severe active rheumatoid arthritis (a joint disease having pain, swelling and stiffness in joints), severe psoriasis (a skin disease that causes rash with itchy scaly patches), severe atopic dermatitis (a skin disease that causes dry itchy and inflamed skin). For more information, see Section [1. Why am I using Sandimmun?](#) in the full CMI.

2. What should I know before I use Sandimmun?

Do not use if you have ever had an allergic reaction to Sandimmun or any of the ingredients listed at the end of the CMI.

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 Sandimmun?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sandimmun 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 Sandimmun?

Sandimmun will be given to you in hospital, usually over 2 to 6 hours. Sandimmun will be diluted using appropriate aseptic technique with normal saline or 5% glucose before use.

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

5. What should I know while using Sandimmun?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Sandimmun.If you develop any lumps anywhere on/in your body, or develop any moles, or you notice changes in existing moles, tell your doctor immediately.Limit your exposure to sunlight and UV light.Avoid taking this medicine with grapefruit, grapefruit juice or a fatty meal.Avoid eating large amounts of foods that are high in potassium content.Take special care of your teeth and gums and see your dentist regularly.
Things you should not do	<ul style="list-style-type: none">Do not have any vaccinations without first consulting with your doctor.Do not stop treatment unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">Sandimmun may make you feel sleepy, dizzy, have blurred vision or headaches. Take care driving until you know how it affects you.
Drinking alcohol	<ul style="list-style-type: none">Your doctor may ask you to limit your alcohol intake.
Looking after your medicine	<ul style="list-style-type: none">Sandimmun is usually stored at the hospital or pharmacy.

For more information, see Section [5. What should I know while using Sandimmun?](#) in the full CMI.

6. Are there any side effects?

Sandimmun may increase your risk of infections, cause headache, tiredness, tremors, burning sensation in the hands or feet, excess hair growth, vomiting, feeling sick, swollen or puffy gums, allergic reactions such as hives, rash, itchy skin.

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.

Sandimmun®

Active ingredient(s): ciclosporin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sandimmun. **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 Sandimmun.**

Where to find information in this leaflet:

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

1. Why am I using Sandimmun?

Sandimmun contains the active ingredient ciclosporin. Sandimmun belongs to group of medicines known as immunosuppressive agents. These medicines help to control your body's immune system.

Sandimmun is used for people who have had a kidney, liver or heart transplant, to prevent the body from rejecting a new organ. It does this by blocking the development of special cells which would normally attack the transplanted tissue.

It is also used to treat other conditions which are thought to be caused by a problem with your immune system:

- Nephrotic syndrome (a kidney disease)
- Severe active rheumatoid arthritis (a disease affecting the joints with pain and swelling)
- Severe psoriasis (a skin disease with thickened patches of red skin, often with silvery scales)
- Severe atopic dermatitis (a skin allergy causing dry itchy and inflamed skin).

2. What should I know before I use Sandimmun?

Warnings

Do not use Sandimmun if:

- you are allergic to ciclosporin, polyoxyethylated castor oil (Cremophor® EL, present in the infusion) or any of the ingredients listed at the end of this leaflet.

Symptoms of allergic reactions may include flushing of face or area between neck and abdomen, shortness of breath or difficulty in breathing, coughing up blood, wheezing, blood pressure changes and fast heartbeat.

Your doctor may discontinue the infusion if you develop allergic reactions.

Always check the ingredients to make sure you can use this medicine.

Do not use Sandimmun if you are taking it for non-transplant related conditions and you have:

- uncontrolled high blood pressure
- any uncontrolled infection.

Use in children

Do not give Sandimmun to patients under 16 years of age to treat severe rheumatoid arthritis, psoriasis or atopic dermatitis. However, it can be used in children younger than 16 years of age who have had an organ transplant or who have a kidney disease (nephrotic syndrome).

Check with your doctor if you have:

- Kidney problems - Sandimmun should not be taken by some patients with impaired kidney function.
- Any type of cancer or conditions that may develop into cancer.
- Vaccinations planned as these may be less effective during treatment with Sandimmun. Use of live attenuated vaccines should be avoided.
- Liver problems
- Severe heart, lung or blood vessel disease.

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.

There is an increased risk of problems in the mother and unborn child with the use of Sandimmun or any immunosuppressive therapy in general.

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

Breast-feeding is not recommended if you are on treatment with Sandimmun. Ciclosporin, the main ingredient of the medicine, passes into the breast milk and can cause serious problems for the baby.

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 Sandimmun and affect how it works. Let your doctor know if you are using any of the following drugs:

- Methotrexate, a medicine used to treat rheumatoid arthritis
- Antibiotics, medicines used to treat infections, e.g. erythromycin, clarithromycin, azithromycin,

rifampicin, ciprofloxacin, trimethoprim, gentamicin, tobramycin, vancomycin

- Antibacterial medicines used to treat tuberculosis e.g. nafcillin, rifampicin
- Antifungal medicines, e.g. fluconazole, ketoconazole, itraconazole, voriconazole, amphotericin B, terbinafine
- Tacrolimus, everolimus, sirolimus, mycophenolate sodium, other medicines which are used to suppress the immune system
- Diuretics (water tablets), a medicine that increases your amount of urine passed
- Heart or blood pressure medicines, e.g. lercanidipine, nifedipine, amlodipine, verapamil, diltiazem, nicardipine, bosentan
- Digoxin, a medicine used to treat heart failure
- Statins, medicines used to treat high cholesterol, e.g. simvastatin, atorvastatin, pravastatin
- Fenofibrate, a medicine used to treat high cholesterol
- Probucol, an agent used to lower cholesterol
- Certain medicines used to prevent fits or seizures e.g. carbamazepine, phenytoin
- Corticosteroid e.g. high doses of Methylprednisolone, a medicine used to treat inflammatory diseases such as arthritis, asthma, colitis
- Medicines used to treat gout e.g. colchicine, sulfapyrazone, allopurinol
- NSAIDs (non-steroid anti-inflammatory drugs), used to treat pain e.g. diclofenac, naproxen, indomethacin
- Recombinant human erythropoietin (rhEPO), a medicine used to treat specific types of anaemia
- Repaglinide, a medicine used to treat diabetes
- Cannabidiol (medicinal cannabis)
- Certain medicines used to decrease the amount of acid in your stomach, e.g. cimetidine, ranitidine
- Some oral contraceptives medicines, e.g. levonorgestrel and norethisterone
- Protease inhibitors used to treat HIV
- Etoposide, imatinib, doxorubicin, medicines used to treat certain cancers
- Octreotide, a medicine used to treat a condition called acromegaly, and certain types of cancer
- Cholic acid and derivatives, medicines used to treat gallstones
- Metoclopramide, a medicine used to treat nausea and vomiting
- Orlistat, a medicine used to help with weight loss
- St John's wort, a herbal supplement used to treat conditions such as depression.
- Nefazodone, a medicine used to treat depression.

Consult your doctor or pharmacist if you are taking any other medicines.

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

4. How do I use Sandimmun?

Sandimmun will be prepared and given to you by a doctor or nurse.

If you have any questions about how Sandimmun is given, ask the doctor or nurse who is giving you the infusion.

How much to take

- Your doctor will determine the correct dose for you. It will depend on how much you weigh, what condition you are taking it for, how well Sandimmun works for you, and whether you have any side effects from this medicine.
- Your doctor may adjust your dose based on your response to medicine.

When will I be given Sandimmun

Sandimmun will be given to you in hospital, usually over 2 to 6 hours.

The usual dose starts on the day before your transplant operation and continues for up to two weeks after the operation.

For non-transplant patients who cannot swallow capsules, your doctor will tell you how often an injection is needed.

How the infusion is given:

The IV infusion will be prepared and given to you in hospital. The infusion is given directly into your vein.

If you forget to take Sandimmun

It is important that you receive all your infusions. Let your doctor know as soon as possible if you think you have missed an infusion.

If you are given too much Sandimmun

If you think that you have been given too much Sandimmun, you may need urgent medical attention.

You should immediately:

- tell the nurse giving you the infusion, 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 Sandimmun?

Things you should do

Keep all your medical appointments.

Your doctor will do routine tests to monitor your blood levels, to check how well your kidneys and liver are working, and to decide if your dose needs to be changed.

Limit your exposure to sunlight and UV light.

If you go out in the sun, wear a hat, appropriate protective clothing and use sunscreen with a high protection factor.

This will help prevent the risk of developing skin cancer.

Avoid eating large amounts of foods that are high in potassium content.

Taking Sandimmun can increase the amount of potassium in your blood. Too much potassium will cause unwanted side effects. Check with your doctor or pharmacist if you are not sure what foods contain high amounts of potassium.

Avoid taking this medicine with grapefruit, grapefruit juice or a fatty meal as it may cause unwanted side effects.

Take special care of your teeth and gums and see your dentist regularly.

Sandimmun may increase your risk of gum disease.

Call your doctor straight away if you:

- develop any lumps anywhere on/in your body, or develop any moles, or you notice changes in existing moles.
- become pregnant while having Sandimmun
- experience any symptoms of infection (e.g. fever, sore throat).

Remind any doctor, dentist or pharmacist you visit that you are using Sandimmun.

Things you should not do

- Do not stop treatment unless your doctor or healthcare professional tells you.
- Do not have any vaccinations without first consulting with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sandimmun affects you.

Sandimmun may make you feel sleepy, dizzy, have blurred vision or headaches.

If your child is on Sandimmun, check how the medicine affects them before they ride a bike or do activities that need coordination and concentration.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol while on treatment with Sandimmun may lead to unwanted effects. Your doctor may ask you to limit your alcohol intake.

Looking after your medicine

- Sandimmun will be stored at the hospital or pharmacy.
- If you need to collect the medicine from a pharmacy, store and transport below 30°C.
- Once an ampoule has been opened, the contents should be diluted using appropriate aseptic technique and administered immediately by a healthcare professional. If not administered immediately, the diluted solution can be stored at 2°C to 8°C (under refrigeration), provided that the total duration for

both storage and infusion is less than 24 hours. Discard any unused diluted solution.

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.

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.

Less serious side effects

Less serious side effects	What to do
<p>General problems:</p> <ul style="list-style-type: none">• Fever• Swelling in the hands or feet• Feeling more tired than normal• Headache• Dizziness• Confusion• Feeling of tingling, numbness• Burning sensation in hands and feet (usually during the first week of treatment)• Tremor, shakiness <p>Gastrointestinal problems:</p> <ul style="list-style-type: none">• Loss of appetite• Swelling of the gums• Feeling sick, vomiting• Diarrhoea• Pain or discomfort in the tummy <p>Skin problems:</p> <ul style="list-style-type: none">• Excessive growth of body and facial hair, particularly in women• Acne• Skin rash• Flushing of the face <p>Reproductive system issues:</p> <ul style="list-style-type: none">• Painful or no menstrual periods• Increased breast size in males <p>Muscle problems:</p> <ul style="list-style-type: none">• Muscle cramps	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> Pain or tenderness in the muscles 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Sudden swelling of the face, lips, tongue, or throat; difficulty breathing; rash or hives; feeling faint or dizzy High fever, chills, feeling very unwell, confusion, rapid heartbeat, trouble breathing Unusual bruising or bleeding, frequent infections (fever, chills, sore throat), extreme tiredness or weakness Severe headache, sudden confusion, trouble seeing, hallucinations, difficulty speaking, seizures Severe stomach pain, swelling of the abdomen, vomiting blood, black or bloody stools, yellowing of the skin or eyes Yellowing of the skin or eyes, dark urine, severe tiredness, pain in the upper right side of the abdomen Muscle cramps, weakness, confusion, irregular heartbeat, fainting, seizures Aching muscles, muscle tenderness or weakness, not caused by exercise Little or no urine, bloody or smelly urine New lumps or moles, or changes to existing moles 	<p>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.</p>

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.

Some side effects may not give you any symptoms and can only be found when tests are done.

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. 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 Sandimmun contains

Active ingredient (main ingredient)	ciclosporin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> castor oil - (Cremophor® EL) 65 % ethanol 26 % w/v
Potential allergens	Contains ethanol

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

What Sandimmun looks like

250 mg/5 mL: Clear brown-yellow, oily solution. Supplied in packs of 10 x 5 mL ampoules.

50 mg/1 mL: Clear brown-yellow, oily solution. Supplied in packs of 10 x 1 mL ampoules.

Australian Registration Numbers:

Sandimmun 50mg/1mL ampoule AUST R 13370

Sandimmun 250mg/5mL ampoule AUST R 47290

Who distributes Sandimmun

Sandimmun is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Telephone: 1 800 671 203

Website: www.novartis.com.au

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