

APO-CICLOSPORIN

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-CICLOSPORIN?

APO-CICLOSPORIN contains the active ingredient ciclosporin. APO-CICLOSPORIN is used for people who have had a kidney, heart or liver transplant, to prevent the body from rejecting the new organ. APO-CICLOSPORIN is also used to treat several other conditions which are thought to be caused by a problem with the immune system: kidney disease (nephrotic syndrome), severe case of rheumatoid arthritis, severe case of psoriasis or atopic dermatitis.

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

2. What should I know before I use APO-CICLOSPORIN?

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

3. What if I am taking other medicines?

Some medicines may interfere with APO-CICLOSPORIN 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-CICLOSPORIN?

- Follow all directions given to you by your doctor and pharmacist carefully.
- The dose of APO-CICLOSPORIN is worked out for each person. It will depend on how much you weigh, what condition is being treated, how well APO-CICLOSPORIN works for you, and whether you have any side effects from this medicine.
- Swallow the capsules whole with a full glass of water. Do not chew the capsules.

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

5. What should I know while using APO-CICLOSPORIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-CICLOSPORIN.• You must take this medicine exactly as prescribed so that it will work properly and to prevent unwanted side effects.• Keep all of your doctor's appointments and have any tests done that are ordered by your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take APO-CICLOSPORIN with grapefruit or grapefruit juice• Do not have any vaccinations without first checking with your doctor• Do not use this medicine to treat any other complaints unless your doctor tells you to.• Do not use this medicine to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking APO-CICLOSPORIN until you know how it affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol with APO-CICLOSPORIN
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the foil blister pack until it is time to take them. Store the pack in a cool dry place where the temperature stays below 25°C

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-CICLOSPORIN, even if you do not think it is connected with this medicine. For more detailed information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-CICLOSPORIN

Active ingredient(s): *CICLOSPORIN*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-CICLOSPORIN. **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-CICLOSPORIN.**

Where to find information in this leaflet:

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

1. Why am I using APO-CICLOSPORIN?

APO-CICLOSPORIN contains the active ingredient ciclosporin. APO-CICLOSPORIN is an immunosuppressive agent. These medicines help to control your body's immune system.

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

APO-CICLOSPORIN is also used to treat several other conditions which are thought to be caused by a problem with the immune system:

- a kidney disease called nephrotic syndrome
- severe cases of rheumatoid arthritis (a disease, affecting the joints with pain and swelling)
- severe cases of:
 - psoriasis (a skin disease with thickened patches of red skin, often with silvery scales)
- atopic dermatitis (skin allergies)

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. APO-CICLOSPORIN is only available with a doctor's prescription. It is not addictive.

2. What should I know before I use APO-CICLOSPORIN?

Warnings

Do not use APO-CICLOSPORIN if:

- you are allergic to ciclosporin, or any of the ingredients listed at the end of this leaflet.

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

- APO-CICLOSPORIN has passed the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.
- Do not give APO-CICLOSPORIN to a child under 16 years of age to treat severe rheumatoid arthritis, psoriasis or atopic dermatitis.

There is not enough information to recommend its use for these diseases in children under 16 years of age.

However, APO-CICLOSPORIN can be used in children younger than 16 who have had an organ transplant or who have nephrotic syndrome.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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?](#)

If you have been prescribed APO-CICLOSPORIN for nephrotic syndrome, rheumatoid arthritis, psoriasis or atopic dermatitis, tell your doctor if you also have any of these health problems/ medical conditions:

- high blood pressure that is not controlled
- any uncontrolled infection
- a poorly functioning immune system
- problems with your kidneys or liver
- severe heart, lung or blood vessel disease
- any type of cancer, including skin cancer

Your doctor may not want you to take APO-CICLOSPORIN or may want to take special precautions if you have any of these conditions.

If you are being treated with APO-CICLOSPORIN for psoriasis or atopic dermatitis, you should not concurrently receive UVB-rays or phototherapy.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Experience with APO-CICLOSPORIN in pregnancy is very limited. The use of immunosuppressant medicines, including ciclosporin, during pregnancy has been shown to increase the risk of problems in the mother and the unborn child. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and risks of taking it during pregnancy.

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

Breast-feeding is not recommended since ciclosporin, the active ingredient in APO-CICLOSPORIN, passes into breast milk and may affect your 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.

Many other medicines may be affected by APO-CICLOSPORIN or they may affect how well APO-CICLOSPORIN works. This includes:

- St John's wort, an ingredient in many medicines that you can buy without a prescription from a pharmacy, health food shop or supermarket
- methotrexate, a medicine to treat severe rheumatoid arthritis, some types of cancers, and psoriasis
- antibacterial amino glycoside- type agents (e.g. gentamicin, tobramycin)
- antifungal agents containing amphotericin B
- antibacterial agents containing ciprofloxacin
- cytostatics containing melphalan
- agents used to treat urinary tract infection containing trimethoprim
- medicines used to treat pain (non- steroid anti-inflammatory drugs, e.g. diclofenac)
- acid secretion inhibitors of the H2-receptor antagonist type (e.g. cimetidine, ranitidine), which are used to reduce the amount of acid in your stomach
- other drugs which may affect the kidneys
- antibacterial agents of the macrolide type (e.g. clarithromycin, azithromycin, erythromycin)
- antifungal agents of the azole type (e.g. fluconazole, itraconazole, ketoconazole, voriconazole) or terbinafine
- oral contraceptives (Levonorgestrel and Norethisterone)
- protease inhibitors, used to treat or prevent infections caused by viruses
- imatinib, a medicine used to treat some cancers
- anthracycline anticancer medicines, such as doxorubicin
- certain blood pressure reducing agents of the calcium antagonist type (e.g. nifedipine, amlodipine, verapamil, diltiazem, amiodarone) or of the endothelin receptor antagonist type (e.g. bosentan, ambrisentan)
- certain anticonvulsives, used to prevent fits or seizures (e.g. carbamazepine, phenytoin)
- digoxin, a medicine used to treat heart failure
- colchicine, used to treat gout disease with painful, swollen joints
- HMG-CoA reductase inhibitors (statins), or fibric acid derivatives, which are used to treat high cholesterol

- prednisolone, a corticosteroid used to treat inflammatory diseases such as arthritis, asthma, colitis
- etoposide, used to treat cancer
- repaglinide, used to treat Type II diabetes
- aliskiren, used to treat high blood pressure
- potassium sparing drugs or potassium containing drugs
- triclopidine (a medicine that is used after a stroke)
- octreotide, a medicine used to treat excess growth hormone, relieve the symptoms of certain types of cancer, or having surgery on the pancreas
- orlistat, used to help with weight loss
- danazol, a medicine used to treat menstrual disorders
- allopurinol, a medicine used to treat gout (a disease with painful, swollen joints caused by uric acid crystals)
- metoclopramide, a medicine used to prevent nausea and vomiting
- cholic acid and derivatives, which are used to treat gallstones
- tacrolimus, everolimus, or sirolimus, which are medicines that lower your immunity
- dabigatran, an anticoagulant medicine used to prevent stroke
- mycophenolate sodium or mofetil, which are medicines that lower your immunity
- eltrombopag, medicine to stimulate the formation of new platelets in the blood.

You may need to take 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 APO-CICLOSPORIN.

If you have not told your doctor about any of these things, tell him/ her before you take APO-CICLOSPORIN.

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-CICLOSPORIN.

4. How do I use APO-CICLOSPORIN?

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

If you are changing from Sandimmun® to APO-CICLOSPORIN

Some patients who have been prescribed APO-CICLOSPORIN would have taken Sandimmun in the past. Like APO-CICLOSPORIN, Sandimmun contains the medicine, ciclosporin. APO-CICLOSPORIN, however, is designed to improve the way ciclosporin gets into your

bloodstream. Because of this, your dose of APO-CICLOSPORIN may eventually be less than the dose of Sandimmun you used to take.

If you are changing from Sandimmun to APO-CICLOSPORIN, your doctor will perform some extra blood tests and then decide whether to change your dose of APO-CICLOSPORIN.

Do not change from APO-CICLOSPORIN to Sandimmun or from Sandimmun to APO-CICLOSPORIN unless it is under the strict supervision of your doctor.

Do not take APO-CICLOSPORIN and Sandimmun at the same time.

How much to take / use

- The dose of APO-CICLOSPORIN is worked out for each person. It will depend on how much you weigh, what condition is being treated, how well APO-CICLOSPORIN works for you, and whether you have any side effects from this medicine. Your dose may be changed from time to time.
- Do not remove the capsules from the foil blister pack until you are ready to take them.
- Swallow the capsules whole with a full glass of water.
- Do not chew them.

When to take APO-CICLOSPORIN

- Always take APO-CICLOSPORIN twice a day. It is best to take the doses 12 hours apart if possible. Take them at about the same time each day.
- Taking your doses 12 hours apart and at the same time each day will have the best effect. It will also help you remember when to take them.

How long to take it

Keep taking this medicine for as long as your doctor recommends.

- The length of treatment will depend on what medical condition you have.

For transplant patients:

- you will need to take one or more immunosuppressant medicines for as long as you have the transplanted organ.

For nephrotic syndrome:

- you may take APO-CICLOSPORIN for 3 months to start with. If it helps your condition, your doctor may decide to continue APO-CICLOSPORIN treatment for as long as it helps you and does not cause serious side effects.

For severe rheumatoid arthritis:

- you will usually take APO-CICLOSPORIN for 3 months to start with.

- It may take this long to know whether APO-CICLOSPORIN will help your condition. If APO-CICLOSPORIN is effective, your doctor may then lower the dose and you will continue treatment at the lowest dose that is suitable for you.

For severe psoriasis:

- you will usually take APO-CICLOSPORIN for up to 6 weeks to start with.
- If your condition improves, your doctor may want you to continue treatment at the lowest effective dose. You can only expect to benefit from this medicine while you continue to take it.

For severe atopic dermatitis:

- you will usually take APO-CICLOSPORIN for up to 8 weeks to start with. Once your condition has improved, the dose may be slowly reduced, and in some cases, may even be stopped.
- Once you have stopped taking APO-CICLOSPORIN, your condition is likely to return, although this may take several weeks or months. Your doctor may then want you to start taking APO-CICLOSPORIN again.

If you forget to use APO-CICLOSPORIN

CICLOSPORIN should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then go back to taking it as you normally would.

Otherwise, 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.

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose, contact your doctor as soon as possible.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much APO-CICLOSPORIN

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

Things you should do

Take APO-CICLOSPORIN exactly as your doctor has prescribed.

You must take this medicine exactly as prescribed so that it will work properly and to prevent unwanted side effects.

Make sure that you keep all of your doctor's appointments and have any tests done that are ordered by your doctor.

Your doctor may ask you to have tests from time to time to check how well your kidneys and liver are working. It may be necessary to measure the amount of ciclosporin, as well as the levels of other chemicals (eg. potassium) in your blood. Your blood pressure will also be checked regularly.

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

In some people taking APO-CICLOSPORIN, the amount of potassium in the blood can increase (called hyperkalaemia). The amount of potassium in the blood can also be increased by eating certain foods. Your doctor can tell you which foods to avoid.

If you become pregnant while taking APO-CICLOSPORIN, tell your doctor.

Your doctor can discuss with you the risks of taking it while you are pregnant.

If you develop lumps anywhere on/ in your body, or develop any moles, or you notice changes in existing moles, tell your doctor.

This may be an early sign of a cancer. Immunosuppressant medicines, including APO-CICLOSPORIN, may increase the risk of developing certain cancers, including skin cancer and lymphoma (cancer of the lymphatic system).

Limit your exposure to sunlight and UV light. If you go out in the sun, wear a hat, appropriate protective clothing and a sunscreen with a high protection factor.

This will help to prevent the development of skin cancer.

If you have psoriasis or atopic dermatitis, you must be especially careful about developing skin cancer. Visit your skin specialist regularly for check-ups.

Take special care of your teeth and gums.

If you experience any symptoms of infection (e.g. fever, sore throat), inform your doctor immediately.

People taking immunosuppressant medicines are at a greater risk of getting infections. Taking good care of your teeth and gums will help to prevent dental and mouth infections.

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

Tell any other doctor, dentist or pharmacist who treats you that you are taking APO-CICLOSPORIN.

Call your doctor straight away if you:

- Become pregnant while you are taking this medicine.
- Experience any symptoms of infection (e.g. fever, sore throat)
- Remind any doctor, dentist or pharmacist you visit that you are using APO-CICLOSPORIN.

Things you should not do

- **Do not take APO-CICLOSPORIN with grapefruit or grapefruit juice since this can influence APO-CICLOSPORIN's effects.**
- **Do not have any vaccinations without first checking with your doctor.**
Some vaccines may be less effective or they may cause unwanted side effects while you are taking APO-CICLOSPORIN.
- **Do not give this medicine to anyone else even if their condition seems similar to yours.**
- **Do not take it to treat any other complaints unless your doctor tells you to.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-CICLOSPORIN affects you.

This medicine can cause tiredness, lack of energy or confusion in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

APO-CICLOSPORIN capsules contain ethyl lactate 28.0% w/w. An oral dosage of 100mg of ciclosporin would result in 129mg of alcohol (ethanol).

Alcohol may be harmful for those suffering from alcoholism, epilepsy, brain injury or liver disease as well as for pregnant or breast-feeding women and children.

Like other medicines that dampen the immune system, ciclosporin may influence your body's ability to fight.

Looking after your medicine

- Keep your capsules in the foil blister pack until it is time to take them. If you take the capsules out of the blister pack, they will not keep well.
- Store the pack 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)

If your doctor tells you to stop taking APO-CICLOSPORIN or it has passed its 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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-CICLOSPORIN, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Your doctor may be able to relieve some of the side effects of APO-CICLOSPORIN by lowering the dose.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

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
<ul style="list-style-type: none"> • tiredness, lack of energy • burning feeling in hands and feet, usually during the first week of treatment • excessive growth of body and facial hair • overgrown, thickened, swollen or bleeding gums • stomach upset, including nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach cramps, stomach ulcer • tremor (shaking) • headache, including migraine • sensitivity to light • weight loss or gain • feeling depressed (sad) • flushing of face, acne, darkening of skin • painful menstrual periods or lack of periods 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you. [Insert appropriate action]</p>

<ul style="list-style-type: none"> • increase in size of breasts in males and females • muscle cramps, tenderness or weakness • blocked or stuffy nose • pain of lower extremities 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • fever (temperature above 37°C) • constant "flu-like" symptoms such as chills, sore throat, aching joints, swollen glands, or any other signs of infection • unusual bleeding or bruising • signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing • new lumps or moles, or changes to existing moles, anywhere on the body • swelling of the eyelids, hands or feet due to excess fluid • a change in the amount of urine passed or in the number of times you urinate, pain on urinating, bloody or smelly urine • yellowing of the skin and/or eyes (jaundice) often accompanied by generally feeling unwell (for example, tiredness, lack of energy, loss of appetite, nausea and vomiting, pain in the abdomen) • severe pain or tenderness in the stomach or abdomen • vomiting blood or material that looks like coffee grounds; black sticky bowel motions or bloody diarrhoea • unusual tiredness or weakness, which may be accompanied by dizziness, spots before the eyes, shortness of breath and pale skin • numbness or "pins and needles" in the hands and feet • a disturbance in brain function which may cause a variety of symptoms, including personality changes, confusion, disorientation, agitation, inability to sleep, decreased responsiveness, weakness and loss of coordination in arms and legs with or without abnormal speech or eye movements, 	<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>

seizures (fits), clumsiness, memory loss, difficulty speaking or understanding what others say, visual hallucinations (seeing things that are not there) or other problems with vision, coma, paralysis of part or all of the body, stiff neck <ul style="list-style-type: none"> • buzzing or ringing in the ears, difficulty hearing 	
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Some side effects may not give you any symptoms and can only be found when tests are done	What to do
<ul style="list-style-type: none"> • changes in kidney or liver function, or liver injury (with or without yellow eyes or skin) • raised blood pressure • increase in the amount of potassium or cholesterol in the blood • decrease in the amount of magnesium in the blood • increase in the amount of uric acid in the blood, which can lead to gout • increase in blood sugar • low white blood cell count • low levels of red blood cells • low levels of platelets in the blood 	<p>Your doctor will make sure that tests are done regularly to watch for these side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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. 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-CICLOSPORIN contains

Active ingredient (main ingredient)	Each APO-CICLOSPORIN capsule contains 25 mg, 50 mg or 100 mg of ciclosporin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Polysorbate 20 • Sorbitan oleate • Lecithin • Tricaprin • PEG-40 castor oil • Ethyl lactate • gelatin • glycerol • Iron Oxide black (E172) • Titanium dioxide
Potential allergens	Sulfites & Soya beans products

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

What APO-CICLOSPORIN looks like

APO-CICLOSPORIN 25 mg capsules: AUST R 324119
Grey soft gelatin capsules filled with an oily liquid solution

APO-CICLOSPORIN 50 mg capsules: AUST R 324111
Grey soft gelatin capsules filled with an oily liquid solution

APO-CICLOSPORIN 100 mg capsules: AUST R 324107
Grey soft gelatin capsules filled with an oily liquid solution

Who distributes APO-CICLOSPORIN

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

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