

Tacrolimus 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 using Tacrolimus Sandoz?

Tacrolimus Sandoz contains the active ingredient tacrolimus monohydrate.

Tacrolimus Sandoz is used so that your new liver, kidney, lung or heart will not be attacked or rejected by your body.

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

2. What should I know before I use Tacrolimus Sandoz?

Do not use if you have ever had an allergic reaction to Tacrolimus Sandoz, macrolide antibiotics, or any of the ingredients listed at the end of the CMI. Tacrolimus Sandoz and Tacrolimus XR Sandoz are not interchangeable.

For more information, see Section [2. What should I know before I use Tacrolimus Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tacrolimus Sandoz and affect how it works.

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.

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 Tacrolimus Sandoz?

- Tacrolimus Sandoz capsules should be taken in two doses (e.g. morning or evening) each day.
- Tacrolimus Sandoz capsules should be taken at least 1 hour before or 2 to 3 hours after a meal preferably with water and not grapefruit juice.

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

5. What should I know while using Tacrolimus Sandoz?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you become pregnant while taking Tacrolimus Sandoz.• Tacrolimus Sandoz suppresses your immune system by lowering your body's immune defence system. This increases your risk of skin cancer and other cancers while taking Tacrolimus Sandoz. You should always protect yourself from the sun, wear sunscreen, a hat and protective clothing.
Things you should not do	<ul style="list-style-type: none">• Do not take Tacrolimus Sandoz to treat any other complaints unless your doctor says so.• Do not give your medicine to anyone else, even if their symptoms are similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Tacrolimus Sandoz may cause visual or nervous disturbances. If affected, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store Tacrolimus Sandoz capsules in a cool dry place where the temperature is below 30°C.

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: signs of allergy; fever; diabetes / increased blood sugar; swelling, numbness or tingling in your hands and feet; constant "flu-like" symptoms; unusual bleeding or bruising; high blood pressure; palpitations, abnormal heart rhythms, chest pain; new lumps or moles, or changes to existing moles; 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, or other kidney problems; yellowing of the skin and/or eyes (jaundice); symptoms of anaemia; seizures (fits); buzzing or ringing in the ears, difficulty hearing.

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.

Tacrolimus Sandoz®

Active ingredient(s): *tacrolimus monohydrate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Tacrolimus Sandoz?

Tacrolimus Sandoz contains the active ingredient **tacrolimus monohydrate**, which is an immunosuppressive agent.

You have been given a new transplanted liver or kidney, lung or heart from another person because your own was no longer healthy. Your body recognises that this new organ is different from your other organs and will try to reject it by attacking it in the same way that it would attack germs that enter your body. This could make you become ill again. Tacrolimus Sandoz stops this attack; it is very important to take Tacrolimus Sandoz given to you by your doctor regularly so you're your new liver, kidney, lung or heart will not be attacked or rejected.

If you have been taking other medicines for this purpose, but are still feeling unwell, your doctor may change your treatment and begin giving you Tacrolimus Sandoz.

Your doctor may have prescribed Tacrolimus Sandoz for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Tacrolimus Sandoz?

Warnings

Do not use Tacrolimus Sandoz if:

- you are allergic to any medicine containing tacrolimus, or other macrolides (these are antibiotics of the erythromycin family), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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 use Tacrolimus Sandoz if the packaging is torn or shows signs of tampering. Do not use Tacrolimus Sandoz beyond the expiry date printed on the pack.

Check with your doctor if you:

- are receiving ciclosporin immunosuppressive therapy.

If you have not told your doctor about any of the above, tell them before you start taking or are given Tacrolimus Sandoz.

Your doctor will advise you whether or not to take Tacrolimus Sandoz or if you need to adjust the dose or adapt your treatment.

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.

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

Check with your doctor if you are using oral contraceptives.

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 Tacrolimus Sandoz and affect how it works.

In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- antifungal medicines and antibiotics, particularly so-called macrolide antibiotics, used to treat infections e.g., ketoconazole, fluconazole, itraconazole, voriconazole, clotrimazole, miconazole, caspofungin, erythromycin, clarithromycin, josamycin, rifampicin, rifabutin and isoniazid
- letermovir, used to prevent illness caused by CMV (human cytomegalovirus)

- HIV protease inhibitors (e.g., ritonavir, nelfinavir, saquinavir), the booster medicine cobicistat, and combination tablets, or HIV non-nucleoside reverse transcriptase inhibitors (efavirenz, etravirine, nevirapine) used to treat HIV infection

- HCV protease inhibitors (e.g., telaprevir, boceprevir, the combination ombitasvir/paritaprevir/ritonavir with or without dasabuvir, elbasvir/grazoprevir, and glecaprevir/pibrentasvir), used to treat hepatitis C infection

- mycophenolic acid used to suppress the immune system to prevent transplant rejection

- medicines for stomach ulcer and acid reflux (e.g., omeprazole, lansoprazole or cimetidine)

- antiemetics, used to treat nausea and vomiting (e.g., metoclopramide)

- cisapride or the antacid magnesium-aluminium-hydroxide, used to treat heartburn

- the contraceptive pill or other hormone treatments with ethinylestradiol, hormone treatments with danazol

- medicines used to treat high blood pressure or heart problems (e.g., nifedipine, nicardipine, diltiazem and verapamil)

- anti-arrhythmic drugs (amiodarone) used to control arrhythmia (uneven beating of the heart)

- medicines known as “statins” used to treat elevated cholesterol and triglycerides

- carbamazepine, phenytoin or phenobarbital, used to treat epilepsy

- metamizole, used to treat pain and fever

- the corticosteroids prednisolone and methylprednisolone, belonging to the class of corticosteroids used to treat inflammations or suppress the immune system (e.g., in transplant rejection)

- nefazodone, used to treat depression

- herbal preparations containing St. John’s wort (*Hypericum perforatum*) or extracts of *Schisandra sphenanthera*.

Tell your doctor if you are taking or need to take ibuprofen, amphotericin B, antibiotics (cotrimoxazole, vancomycin, or so-called aminoglycoside antibiotics such as gentamicin), or antivirals (e.g., acyclovir, ganciclovir, cidofovir, or foscarnet). These may worsen kidney or nervous system problems when taken together with Tacrolimus Sandoz.

Your doctor also needs to know if you are taking potassium supplements or potassium-sparing diuretics (e.g., amiloride, triamterene, or spironolactone), or the antibiotics trimethoprim or cotrimoxazole that may increase levels of potassium in your blood, certain pain killers (so-called NSAIDs, e.g., ibuprofen), anticoagulants, or oral medication for diabetic treatment, while you receive Tacrolimus Sandoz.

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

4. How do I use Tacrolimus Sandoz?

How much to take

- You can only get Tacrolimus Sandoz from your doctor. Your dose will be calculated according to your weight, age and medical condition. As your health and the function of your new liver or kidney, lung or heart can be affected by how much medicine you take, it is normal that your doctor collects samples of blood and urine at regular intervals. This is in order to test whether your medicine requires adjustment.

When to take Tacrolimus Sandoz

- Tacrolimus Sandoz should be taken in two doses (e.g. morning and evening) each day.

How to take Tacrolimus Sandoz

- Take the capsule from the blister pack and swallow it whole with plenty of water. Do not take this medicine with grapefruit juice as it contains substances that interfere with the action of Tacrolimus Sandoz.
- Tacrolimus Sandoz capsules should generally be taken on an empty stomach or at least 1 hour before a meal or 2 to 3 hours after a meal. You must never change the dose yourself even if you are feeling better. It is very important that you keep taking this medicine so that your body will not reject your new liver, kidney lung or heart.
- If you accidentally take a larger dose than recommended, tell your doctor immediately.
- If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

How long to take Tacrolimus Sandoz

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

If you forget to use Tacrolimus 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.

Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or 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 use too much Tacrolimus Sandoz

If you think that you have used too much Tacrolimus 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 764 766), 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 Tacrolimus Sandoz?

Things you should do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while taking Tacrolimus Sandoz.
- Tacrolimus Sandoz suppresses your immune system by lowering your body's immune defence system. This increases your risk of skin cancer and other cancers while taking Tacrolimus Sandoz. You should always protect yourself from the sun, wear sunscreen, a hat and protective clothing.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tacrolimus Sandoz.

Remind any doctor, dentist or pharmacist you visit that you are using Tacrolimus XR Sandoz.

Things you should not do

- Do not take Tacrolimus Sandoz to treat any other complaints unless your doctor says so.
- Do not give your medicine to anyone else, even if their symptoms are similar to yours.

Driving or using machines

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

Tacrolimus Sandoz may cause visual or nervous disturbances in some people. If affected, do not drive or operate machinery.

Effects of food and alcohol

Food reduces the absorption of Tacrolimus Sandoz. Therefore, the capsules should be taken at least 1 hour before a meal or 2 to 3 hours after a meal.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Use all the Tacrolimus Sandoz capsules within 12 months of opening the aluminum wrapper. Do not use after printed expiry date.
- Keep Tacrolimus Sandoz capsules in the blisters until it is time to take them. If you take it out of its original container it may not keep well.

- Store Tacrolimus Sandoz capsules where temperatures stay below 30°C.
- Protect from light and moisture.

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.

Heat and dampness can destroy some medicines.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<p>General</p> <ul style="list-style-type: none"> • tiredness, lack of energy <p>Gut or Gastrointestinal related</p> <ul style="list-style-type: none"> • stomach upset, including nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach cramps <p>Brain related</p> <ul style="list-style-type: none"> • tremor (shaking) • headache • feeling depressed (sad) • sleeping difficulties <p>Eye related</p> <ul style="list-style-type: none"> • blurred vision or sensitive to light <p>Muscles related</p> <ul style="list-style-type: none"> • muscle cramps, tenderness or weakness. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing <p>Infection related</p> <ul style="list-style-type: none"> fever constant "flu-like" symptoms such as chills, sore throat, fever, aching joints, swollen glands, or any other signs of infection, or 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) <p>Blood related</p> <ul style="list-style-type: none"> unusual bleeding or bruising symptoms of anaemia, such as shortness of breath, tiredness, or dizziness fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice), with symptoms of acute renal failure (low or no urine output). <p>Heart related</p> <ul style="list-style-type: none"> palpitations, abnormal heart rhythms, chest pain or high blood pressure <p>Skin related</p> <ul style="list-style-type: none"> new lumps or moles, or changes to existing moles, anywhere on the body <p>Kidneys related</p> <ul style="list-style-type: none"> a change in the amount of urine passed or in the number of times you urinate, pain on urinating, or other kidney problems <p>Liver related</p> <ul style="list-style-type: none"> 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) 	<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>

<p>Head or brain related</p> <ul style="list-style-type: none"> seizures (fits) buzzing or ringing in the ears, difficulty hearing. <p>Others</p> <ul style="list-style-type: none"> diabetes / increased blood sugar swelling, numbness or tingling (pins and needles) in your hands and feet swelling of the eyelids, hands or feet due to excess fluid high blood pressure 	
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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. Tell your doctor if you notice any other side effects.

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 www.medsafe.govt.nz/safety/report-a-problem.asp. 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 Tacrolimus Sandoz contains

Active ingredient (main ingredient)	tacrolimus monohydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> hypromellose lactose monohydrate croscarmellose sodium magnesium stearate titanium dioxide (0.5 mg, 0.75 mg, 1 mg & 2 mg capsule only) sodium lauryl sulfate (0.5 mg, 0.75 mg, 1 mg & 2 mg capsule only) sorbitan monolaurate (0.5 mg, 0.75 mg, 1 mg & 2 mg capsule only) gelatin (0.5 mg, 0.75 mg, 1 mg & 2 mg capsule only) shellac (0.5 mg, 1 mg & 5 mg capsule only)

	<ul style="list-style-type: none"> • iron oxide yellow (0.5 mg, 0.75 mg, 1 mg & 2 mg capsule only) • iron oxide red (1 mg, 2 mg & 5 mg capsule only) • iron oxide black (0.5 mg, 1 mg & 5 mg capsule only). • brilliant blue FCF (0.75 mg & 2 mg capsule only). • TekPrint SW-9008 black ink or TekPrint SW-9009 black ink (0.75 mg & 2 mg capsule only).
Potential allergens	<ul style="list-style-type: none"> • lactose

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

What Tacrolimus Sandoz looks like

- Tacrolimus Sandoz 0.5 mg - White and ivory opaque capsule. (AUST R 153744)
- Tacrolimus Sandoz 0.75 mg – Light green opaque body and cap, imprinted in black with 0.75 mg on cap. (AUST R 229738)
- Tacrolimus Sandoz 1 mg - White and light brown opaque capsule. (AUST R 153745)
- Tacrolimus Sandoz 2 mg – Dark green opaque body and cap, imprinted in black with 2 mg on cap. (AUST R 229757)
- Tacrolimus Sandoz 5 mg - White and orange opaque capsule. (AUST R 153746)

Available in packs of 100 (0.5 mg/0.75 mg/1 mg/2 mg) or 50 (5 mg) capsules.

**Not all presentations and strengths may be marketed in Australia and New Zealand.*

Who distributes Tacrolimus Sandoz

Australia

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

New Zealand

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

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