

Tacrolimus Sandoz®; Tacrolimus XR Sandoz®

tacrolimus monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tacrolimus 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 this medicine is expected to 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 need to read it again.

What Tacrolimus Sandoz is used for

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.

Tacrolimus Sandoz contains the active ingredient tacrolimus.

Tacrolimus belongs to a group of medicines called macrolide lactones, which is an immunosuppressive agent. It is very important to take Tacrolimus Sandoz, given to you by your doctor, regularly so that your new liver, kidney, lung or heart will not be attacked or rejected.

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.

Before you take Tacrolimus Sandoz

When you must not take it

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

- tacrolimus, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description
- any other macrolides (these are antibiotics of the erythromycin family, e.g. Eryc, EES, Klacid, Zithromax, Rulide or Biaxsig).

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 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 or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if:

- you are using oral contraceptives
- you are receiving ciclosporin immunosuppressive therapy.

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

This is particularly important for Tacrolimus Sandoz because there are some specific medicines that could alter its effectiveness and safety.

Some medicines and Tacrolimus Sandoz may interfere with each other. These include:

- St John's Wort (hypericum perforatum), a herbal preparation which is capable of decreasing tacrolimus blood levels
- antifungal agents such as ketoconazole, fluconazole, itraconazole, voriconazole
- erythromycin (macrolide antibiotic)
- HIV protease inhibitors (e.g. ritonavir)
- clotrimazole
- clarithromycin
- josamycin
- nifedipine
- nicardipine
- diltiazem
- verapamil
- danazol
- ethinylestradiol
- omeprazole
- nefazodone
- rifampicin
- phenytoin
- ciclosporin
- steroid-based contraceptives
- potassium sparing diuretics (e.g. amiloride, triamterene or spironolactone)
- live attenuated vaccines.

These medicines may be affected by Tacrolimus 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.

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.

How to take Tacrolimus 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

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.

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, Tacrolimus Sandoz may not work as well and your problem may not improve.

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.

How to take it

Take the capsule from the blister pack and swallow it whole with plenty of water.

Do not take this medicine with grapefruit juice.

Grapefruit juice contains substances that interfere with the action of Tacrolimus Sandoz.

When to take Tacrolimus Sandoz

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

The total daily amount should be divided and taken in two doses (e.g. morning and evening).

How long to take Tacrolimus Sandoz

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

It is important to keep taking your medicine even if you feel well.

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 accidentally take a larger dose than recommended, tell your doctor immediately.

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 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 764766) 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 Tacrolimus Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Tacrolimus Sandoz

Things you must do

Always follow your doctor's instructions carefully.

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. 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.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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

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

Your doctor may collect samples of blood and urine at regular intervals to make sure the medicine is working, to prevent unwanted side effects and to test whether your medicine requires adjustment.

Things you must not do

Do not take Tacrolimus 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.

Things to be careful of

Be careful driving or operating machinery until you know how Tacrolimus Sandoz affects you.

This medicine may cause visual or nervous disturbances in some people. If affected, do not drive or operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tacrolimus 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.

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:

- tiredness, lack of energy
- stomach upset, including nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach cramps
- tremor (shaking)
- headache
- feeling depressed (sad)
- sleeping difficulties
- blurred vision or sensitive to light
- muscle cramps, tenderness or weakness.

These are mild side effects of the medicine and are short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

- fever
- diabetes / increased blood sugar
- swelling, numbness or tingling (pins and needles) in your hands and feet
- 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)
- unusual bleeding or bruising, or new lumps or moles, or changes to existing moles, anywhere on the body
- palpitations, abnormal heart rhythms, chest pain or high blood pressure
- 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
- symptoms of anaemia, such as shortness of breath, tiredness or dizziness
- seizures (fits)
- buzzing or ringing in the ears, difficulty hearing.

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

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other side effects.

After taking Tacrolimus Sandoz

Storage

Keep your medicine in the blisters until it is time to take them. 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.

After opening of the aluminium wrapping, store below 25°C and use within twelve months. Do not use after printed expiry date.

Do not store Tacrolimus 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

Tacrolimus Sandoz comes in five types of capsules:

Tacrolimus Sandoz 0.5 mg - White and ivory opaque capsule.

Tacrolimus Sandoz 0.75 mg - Light green opaque body and cap, imprinted in black with 0.75 mg on cap.

Tacrolimus Sandoz 1 mg - White and light brown opaque capsule.

Tacrolimus Sandoz 2 mg - Dark green opaque body and cap, imprinted in black with 2 mg on cap.

Tacrolimus Sandoz 5 mg - White and orange opaque capsule.

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

Not all strengths may be marketed in Australia.

Not all strengths may be marketed in New Zealand.

Ingredients

Active ingredients:

- Tacrolimus Sandoz 0.5 mg - 0.5 mg tacrolimus (as monohydrate)
- Tacrolimus Sandoz 0.75 mg - 0.75 mg tacrolimus (as monohydrate)
- Tacrolimus Sandoz 1 mg - 1 mg tacrolimus (as monohydrate)
- Tacrolimus Sandoz 2 mg - 2 mg tacrolimus (as monohydrate)
- Tacrolimus Sandoz 5 mg - 5 mg tacrolimus (as monohydrate)

Inactive ingredients:

- 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)
- 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).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Novartis New Zealand Ltd
PO Box 99102
Newmarket
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New Zealand
Tel: 0800 354 335

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Australian Register Numbers

0.5 mg capsules: AUST R 153744

0.75 mg capsules: AUST R 229738

1 mg capsules: AUST R 153745

2 mg capsules: AUST R 229757

5 mg capsules: AUST R 153746