

Tacrolimus APOTEX

Contains the active ingredient tacrolimus

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Tacrolimus APOTEX Capsules. 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 Tacrolimus APOTEX against the benefits this medicine is expected to have for you.

If you have any concerns about using Tacrolimus APOTEX ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What this medicine is used for

Tacrolimus APOTEX contains the active ingredient tacrolimus, 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 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 APOTEX stops this attack; it is very important to take Tacrolimus APOTEX given to you by your doctor regularly so that 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 APOTEX.

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

Your doctor may have prescribed Tacrolimus APOTEX for another reason.

Before you take this medicine

When you must not take it

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

- any medicine containing tacrolimus
- other macrolides (these are antibiotics of the erythromycin family)
- any of the ingredients contained in the capsules

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 if you are pregnant.

There are no adequate safety studies in pregnant women and tacrolimus may affect your developing baby if you take it during pregnancy.

You and your partner should consider appropriate and adequate contraception prior to starting treatment with tacrolimus.

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

Do not breastfeed if you are taking this medicine.

Tacrolimus passes into breast milk and there is a possibility that your baby may be affected.

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 receiving cyclosporin immunosuppressive therapy.

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.

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

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, as there are some specific medicines that could alter its effectiveness and safety. These include:

- oral contraceptives
- St John's Wort (*Hypericum perforatum*)
- clotrimazole, ketoconazole, fluconazole, miconazole, itraconazole and voriconazole, antifungal medications
- clarithromycin or erythromycin, antibiotic medications
- ritonavir, nelfinavir, saquinavir, telaprevir, boceprevir or letermovir, antiviral medications
- amiodarone, diltiazem, verapamil, quinidine or nifedipine, used to treat heart conditions
- lansoprazole or omeprazole, used to treat stomach problems
- cyclosporin
- grapefruit juice

Other medications not listed above may interact with tacrolimus.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

They can also tell you what to do if you are taking any of these medicines.

Effects on driving and operating machinery

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

Effects of food and alcohol

Food reduces the absorption of tacrolimus, so the capsules should be taken at least 1 hour before a meal.

How to take this medicine

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 directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine to take.

Tacrolimus should be taken in two doses (e.g. morning and evening).

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 to test whether your medicine requires adjustment.

How to take it

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

Do not use grapefruit juice as it contains substances that interfere with the action of tacrolimus.

Tacrolimus capsules should be taken at least 1 hour before a meal.

How long to take it for

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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 have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

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

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.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Always protect yourself from the sun, wear sunscreen, a hat and protective clothing.

Tacrolimus suppress your immune system by lowering your body's immune defence system. This increases your risk of skin cancer and other cancers while taking this medicine.

Things you must not do

Do not take this medicine 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 stop taking your medicine or change the dosage without checking with your doctor.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

- 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

Tell your doctor as soon as possible if you notice any of the following:

- 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, aching joints, swollen glands, or any other signs of infection
- unusual bleeding or bruising
- high blood pressure
- palpitations, abnormal heart rhythms, chest pain
- 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, or other kidney problems.

- 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)
- symptoms of anaemia, such as shortness of breath, tiredness or dizziness
- seizures (fits)
- buzzing or ringing in the ears, difficulty hearing
- vision problems (optic neuropathy)
- pain in your limbs that may occur as severe, disabling, bilateral leg pain with skin itching
- 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

The above list includes serious side effects that may require medical attention.

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

Other side effects not listed above may also occur in some people.

Some of these side effects, such as changes to your blood count, can only be found when your doctor does tests from time to time to check your progress.

Storage and disposal

Storage

Use all the capsules within 12 months of opening the aluminium wrapper.

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

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill 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

What Tacrolimus APOTEX Capsules look like

Tacrolimus APOTEX capsules 0.5 mg

White to off white powder filled in size '5' yellow coloured cap/yellow coloured body hard gelatin capsule printed with "0.5 mg" on cap and "Tacro" on body with red ink. AUST R 209273.

Available in blister sheets of ten capsules and sealed in an aluminium wrapper (Pack size 100 capsules).

Tacrolimus APOTEX 1 mg capsules

White to off white powder filled in size '5' white coloured cap/white coloured body hard gelatin capsule printed with "1 mg" on cap and "Tacro" on body with red ink. AUST R 209275.

Available in blister sheets of ten capsules and sealed in an aluminium wrapper (Pack size 100 capsules).

Tacrolimus APOTEX 5 mg capsules

White to off white powder filled in size '4' greyish red coloured cap/greyish red coloured body hard gelatin capsule printed with "5 mg" on cap and "Tacro" on body with white ink. AUST R 209269.

Available in blister sheets of ten capsules and sealed in an aluminium wrapper (Pack size 50 capsules).

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 0.5 mg, 1 mg or 5 mg of tacrolimus as the active ingredient.

It also contains the following inactive ingredients:

- hypromellose
- croscarmellose sodium
- lactose anhydrous
- magnesium stearate
- TekPrint SB-1033 Red Ink (0.5 mg and 1 mg strengths only)
- TekPrint SW-0012 White ink (5 mg strength only)

The capsule shells contain:

- gelatin
- water
- titanium dioxide
- sodium lauryl sulfate
- iron oxide yellow (0.5 mg strength only)
- iron oxide red (5 mg strength only)

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Distributor

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