

TACROCORD CAPSULES

Tacrolimus (0.5mg, 1mg, 5mg)

What is in this leaflet

1. What Tacrocord is used for
2. How Tacrocord works
3. Before you use Tacrocord
4. How to use Tacrocord
5. While you are using it
6. Side effects
7. Storage and Disposal of Tacrocord
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Tacrocord is used for

Following your organ transplant (e.g. liver, kidney, heart), your body's immune system will try to reject the new organ. Tacrocord is used to control your body's immune response enabling your body to accept the transplanted organ.

Tacrocord is often used in combination with other medicines that also suppress the immune system.

You may also be given Tacrocord for an ongoing rejection of your transplanted liver and kidney or if any previous treatment you were taking was unable to control this immune response after your transplantation.

Only for Tacrolimus Capsules 0.5mg and 1mg

Tacrocord is also used for lupus nephritis (a disease whereby body own immune system targets the kidneys and causes damage to the kidneys) when effect of steroids is not adequate or administration of steroids is difficult because of their side effects.

How Tacrocord works

Tacrocord consists of active ingredient tacrolimus. It belongs to a group of medicines called immunosuppressants. It is used to control your body's immune response by preventing your body to reject the transplanted organ.

Before you use Tacrocord

When you must not use it

- If you are allergic (hypersensitive) to tacrolimus or any of the other ingredients of Tacrocord.
- If you are allergic (hypersensitive) to macrolide antibiotics such as erythromycin, clarithromycin and josamycin.
- If you are pregnant or think you may be pregnant or are planning to have a baby
- If you are breastfeeding as Tacrocord is excreted in the breast milk.
- If you have intolerance to some sugars as Tacrocord contains lactose.

Before you start to use it

Talk to your doctor or pharmacist before taking Tacrocord:

- If you have liver problems or have had a disease which may have affected your liver, please tell your doctor as this may affect the dose of Tacrocord that you receive.
- If you feel strong abdominal pain accompanied or not with other symptoms, such as chills, fever, nausea or vomiting.
- If you have diarrhoea for more than one day, please tell your doctor, because it might be necessary to adapt the dose of Tacrocord that you receive.
- If you have an alteration of the electrical activity of your heart called "QT prolongation".

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal remedies.

Tacrocord must not be taken with ciclosporin.

Tacrocord blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking Tacrocord which may require interruption, an increase or a decrease in

Tacrocord dose. In particular, you should tell your doctor if you are taking or have recently taken medicines with active substances like:

- antifungal medicines and macrolide antibiotics, used to treat infections e.g., ketoconazole, fluconazole, itraconazole, clotrimazole, voriconazole, erythromycin, clarithromycin, josamycin, and rifampicin.
- HIV protease inhibitors (e.g., ritonavir, nelfinavir, saquinavir), used to treat HIV infection
- HCV protease inhibitors (e.g. telaprevir, boceprevir), used to treat hepatitis C infection
- medicines for stomach ulcer and acid reflux (e.g. omeprazole, lansoprazole or cimetidine)
- antiemetics, used to treat nausea and vomiting (e.g. metoclopramide)
- magnesium-aluminium-hydroxide (antacid), used to treat heartburn
- hormone treatments with ethinylestradiol (e.g. the oral contraceptive pill) or danazol
- medicines for high blood pressure or heart problems such as nifedipine, nicardipine, diltiazem and verapamil
- anti-epileptic medicines such as phenytoin, phenobarbital and carbamazepine
- corticosteroids such as prednisolone and methylprednisolone
- anti-depressant such as nefazodone
- Herbal preparations containing St. John's Wort

Tell your doctor if you are taking or need to take ibuprofen, amphotericin B, or antivirals (e.g. aciclovir). These may worsen kidney or nervous system problems when taken together with Tacrocord.

Your doctor also needs to know if you are taking potassium supplements or potassium-sparing diuretics (e.g., amiloride, triamterene, or spironolactone), certain pain killers (so-called NSAIDs, e.g., ibuprofen), oral anticoagulants, or

TACROCORD CAPSULES

Tacrolimus (0.5mg, 1mg, 5mg)

oral medication for diabetic treatment, while you take Tacrocord.

Taking with food and drinks

Grapefruit or grapefruit juice should be avoided when taking Tacrocord.

How to use Tacrocord

How much to use

Always take Tacrocord exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Make sure that you receive the same tacrolimus medicine every time you collect your prescription, unless your transplant specialist has agreed to change to a different brand of tacrolimus medicine.

Initial doses just after transplantation will generally be in the range of 0.10 – 0.30 mg per kg body weight per day depending on the transplanted organ.

Only for Tacrolimus Capsules 0.5mg and 1mg

For adults, usually, a dose of 3mg as tacrolimus will be given, once daily after supper.

Your dose depends on your general condition and on which other immunosuppressive medication you are taking. Regular blood tests by your doctor will be required to define the correct dose and to adjust the dose from time to time. Your doctor will usually reduce your tacrolimus dose once your condition has been stabilised. Your doctor will tell you exactly how many capsules to take and how often.

When to use it

Always take Tacrocord exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How long to use it

Continue taking Tacrocord for as long as your doctor recommends.

If you forget to use it

Do not take a double dose to make up for forgotten individual doses.

If you have forgotten to take your Tacrocord capsules, wait until it is time for the next dose, and then continue as before.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause tremor, headache, nausea and vomiting, infections, hives, lethargy, increase in blood levels of urea and creatinine (urea and creatinine are waste products of the body), and increase in alanine aminotransferase levels which is related to liver damage.

While you are using it

Things you must do

- Inform your doctor, dentist and pharmacist that you are taking Tacrocord.
- Tell your doctor immediately if you are pregnant while taking Tacrocord.
- You should keep in regular contact with your doctor. Whilst you are taking Tacrocord, your doctor may want to carry out a number of tests (including blood, urine, heart function, visual and neurological tests) from time to time. This is quite normal and will help your doctor to decide on the most appropriate dose of Tacrocord for you.
- Limit your exposure to sunlight and UV light whilst taking Tacrocord by wearing appropriate protective clothing and using a sunscreen with a high sun protection factor. This is because of the potential risk of malignant skin changes with immunosuppressive therapy.
- If you need to have any vaccinations, please inform your doctor beforehand.

Your doctor will advise you on the best course of action.

Things you must not do

- Do not stop your treatment unless your doctor tells you to do so. Stopping your treatment with Tacrocord may increase the risk of rejection of your transplanted organ.
- Do not start taking any new medication without discussing with your doctor or pharmacist.
- Do not share Tacrocord with anyone who has the same symptom or disease with you.

Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Tacrolimus may cause visual and neurological disturbances. This effect may be enhanced if Tacrocord is administered in association with alcohol.

Side effects

Like all medicines, Tacrocord can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist immediately if you experience any side effects after using the medication.

Tacrolimus reduces your body's own defense mechanism to stop your body from rejecting your transplanted organ. Consequently, your body will not be as good as usual at fighting infections. So if you are taking tacrolimus you may therefore catch more infections than usual such as infections of the skin, mouth, stomach and intestines, lungs and urinary tract.

The side effects listed below may also occur after receiving Tacrocord:

TACROCORD CAPSULES

Tacrolimus (0.5mg, 1mg, 5mg)

Very common side effects:

- Increased blood sugar, diabetes mellitus, increased potassium in the blood
- Difficulty in sleeping
- Trembling, headache
- Increased blood pressure
- Diarrhoea, nausea
- Kidney problems

Common side effects:

- Reduced magnesium, phosphate, potassium, calcium or sodium in the blood, fluid overload, increased uric acid or lipids in the blood, decreased appetite, increased acidity of the blood, other changes in the blood electrolytes
- Anxiety symptoms, confusion and disorientation, depression, mood changes, nightmare, hallucination, mental disorders
- Fits, disturbances in consciousness, tingling and numbness (sometimes painful) in the hands and feet, dizziness, impaired writing ability, nervous system disorders
- Blurred vision, increased sensitivity to light, eye disorders
- Ringing sound in your ears
- Reduced blood flow in the heart vessels, faster heartbeat
- Bleeding, partial or complete blocking of blood vessels, reduced blood pressure
- Difficulty in breathing, changes in the lung tissue, collection of liquid around the lung, throat inflammation, cough, flu-like symptoms
- Inflammations or ulcers causing abdominal pain or diarrhoea, bleedings in the stomach, inflammations or ulcers in the mouth, collection of fluid in the belly, vomiting, abdominal pains, indigestion, constipation, bloating, loose stools, stomach problems
- Changes in liver enzymes and function, yellowing of the skin due to liver problems, liver tissue damage and inflammation of the liver
- Itching, rash, hair loss, acne, increased sweating

- Pain in joints, limbs, back and feet, muscle spasms
- Insufficient function of the kidneys, reduced production of urine, impaired or painful urination
- General weakness, fever, collection of fluid in your body, pain and discomfort, increase of the enzyme alkaline phosphatase in your blood, weight gain, abnormal feeling of body temperature

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Tacrocord

- Storage

Keep Tacrocord out of the sight and reach of children.

Store below 30°C.

Protect from light and moisture.

- Disposal

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

- Tacrocord 0.5 Capsules 0.5 mg- Opaque light yellow color, size "4" hard gelatin capsule imprinted with "C5" "0.5mg" on cap with black ink, with white to off-white granular powder.
- Tacrocord 1 Capsules 1 mg: Opaque white color, size "4" hard gelatin capsules imprinted with "C6" "1mg" on cap with black ink, containing white to off white granular powder.
- Tacrocord 5 Capsules 5 mg: Opaque grayish red color, size "4" hard gelatin capsules imprinted with "C7" "5mg" on cap with black ink,

containing white to off white granular powder.

- Ingredients

-Active ingredient:

Tacrocord 0.5 Capsules 0.5 mg contains 0.5mg of tacrolimus.

Tacrocord 1 Capsules 1 mg contains 1mg of tacrolimus.

Tacrocord 5 Capsules 5 mg contains 5mg of tacrolimus.

-Inactive ingredients:

Tacrocord 0.5 Capsules 0.5 mg:

-Capsule content: Croscarmellose sodium, hypromellose, anhydrous lactose, dehydrated alcohol, methylene chloride, magnesium stearate.

-Capsule shell: Iron oxide yellow (E172), Titanium dioxide (E171), gelatin

-Printing ink of capsule shell: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonium solution, black iron oxide, potassium hydroxide, purified water

Tacrocord 1 Capsules 1 mg:

-Capsule content: Croscarmellose sodium, hypromellose, anhydrous lactose, dehydrated alcohol, methylene chloride, magnesium stearate.

-Capsule shell: Titanium dioxide (E171), gelatin

-Printing ink of capsule shell: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonium solution, black iron oxide, potassium hydroxide, purified water

Tacrocord 5 Capsules 5 mg:

-Capsule content: Croscarmellose sodium, hypromellose, anhydrous lactose, dehydrated alcohol, methylene chloride, magnesium stearate.

-Capsule shell: Iron oxide red (E172), titanium dioxide (E171), gelatin

-Printing ink of capsule shell: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonium solution, black iron oxide, potassium hydroxide, purified water

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MAL number:

Tacrocord 0.5 Capsules 0.5 mg

MALxxxxAZ

Tacrocord 1 Capsules 1 mg

MALxxxxAZ

Tacrocord 5 Capsules 5 mg

MALxxxxAZ

Manufacturer

Concord Biotech Limited
297-298/2p, Siyawada, Valthera,
Ahmedabad, Gujarat 382225, India.

Product Registration Holder

HOVID Berhad
121, Jalan Tunku Abdul Rahman
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12/10/2021

Serial Number

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