# TACROLIMUS MEDIS® 1 mg - TACROLIMUS MEDIS® 5 mg

## INN : Tacrolimus

Please read all of this leaflet carefully before taking this medicine.

-Keep this leaflet, you may need to read it again.

-If you have other questions, if you have any doubt, ask your doctor or pharmacist.

-This medicine has been prescribed for you. Never give it to someone else, even if the symptoms are the same as yours.

-If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:


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### 1.WHAT TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG AND IN WHICH CASES IT IS USED FOR?

TACROLIMUS MEDIS belongs to a class of immunosuppressive drugs.

Following your organ transplant, your immune system will try to reject the new organ. TACROLIMUS MEDIS is used to control the immune response of your body allowing your body to accept the transplanted organ.

TACROLIMUS MEDIS is indicated for:

Primary immunosuppressant in liver and kidney allograft recipients and rejection of the liver and kidney in case of resistance to conventional immunosuppressive regime.

### 2. WHAT YOU SHOULD KNOW BEFORE USING TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG ?

Never use TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG in the following cases:

- If you are allergic (hypersensitive) to tacrolimus or any other ingredients in TACROLIMUS MEDIS;
- If you are allergic (hypersensitive) to any antibiotic belonging to the class of macrolide antibiotics (eg, erythromycin, clarithromycin, josamycin).

Take special care with TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG:

- You must take TACROLIMUS MEDIS every day as long as you need immunosuppression to prevent rejection of a transplanted organ. You should keep in regular contact with your doctor.
- While taking TACROLIMUS MEDIS, it may be that your doctor want to carry out various analyzes (including blood tests, urine tests, exams of heart function, visual and neurological tests). This is quite normal and will help to determine the most appropriate dose of TACROLIMUS MEDIS for you.
- Please avoid taking any herbal medicine (herbal), as millepertuis (Hypericum perforatum) or any other herbal product as this may affect the efficacy and dose TACROLIMUS MEDIS you need. If in doubt, consult your physician before taking any products or herbal medicine.
- If you have livet problems or if you have had a disease that could affect your liver, please inform your doctor as this may affect the dose of TACROLIMUS MEDIS you take.
- If you have diarrhea for more than one day, please tell your doctor because you may need dosage adjustments of TACROLIMUS MEDIS you take.
- Limit your exposure to sunlight and UV rays while taking TACROLIMUS MEDIS by wearing appropriate protective clothing and using a sunscreen with a high protection factor. This because of the potential risk of developing malignant skin tumors with immunosuppressants.
- If you receive a vaccination, talk to your doctor before. He will advise you on what to do.

Taking other medicines:
If you are taking, or have recently taken any other medicines, including medicines obtained without a prescription and herbal medication (herbal), tell your doctor or pharmacist.

TACROLIMUS MEDIS should not be taken with cyclosporine.
Blood concentrations of TACROLIMUS MEDIS can be modified by other medications you are taking and TACROLIMUS MEDIS can affect blood levels of other drugs, which may require an increase or decrease in the dose of TACROLIMUS MEDIS. You must include your doctor if you are taking or have recently taken medicines containing the active substances listed below:

- antifungal and antibiotic medications, especially antibiotics called macrolides, used to treat infections (eg ketoconazole, fluconazole, itraconazole, voriconazole, clotrimazole, erythromycin, clarithromycin, josamycin, and rifampicin);
- inhibitors of HIV protease (eg, ritonavir);
- omeprazole, used to treat stomach ulcers; hormone treatments with ethinylestradiol (eg, the pill) or danazol;
- medicines for high blood pressure or heart problems, such as nifedipine, nicardipine, verapamil and diltiazem;
- medicines known as "statins" used to treat high cholesterol and triglyceride levels;
- Anti-epileptic phenytoin or phenobarbital;
- the corticosteroids prednisolone and methylprednisolone;
- the antidepressant nefazodone;
- the millepertuis (Hypericum perforatum).

Tell your doctor if you are taking, or if you need to take ibuprofen, amphotericin B or antivirals (eg, aciclovir). They can worsen kidney or nerve problems when taken with TACROLIMUS MEDIS.

Your doctor also needs to know if during your treatment with TACROLIMUS MEDIS taking potassium supplements or potassium-sparing diuretics (eg, amiloride, triamterene or spironolactone), certain pain killers (called nonsteroidal anti-inflammatory drugs or NSAIDs, such as the ibuprofen), anticoagulants or oral medications for diabetes.
If you need to get vaccinated, tell your doctor in advance.

Interactions with food and drinks:
Generally TACROLIMUS MEDIS must be taken at fasting (empty stomach) or at least 1 hour before or 2 to 3 hours after a meal.
Avoid eating grapefruit or grapefruit juice during treatment with TACROLIMUS MEDIS.

Pregnancy and lactation :
If you plan to become pregnant or think you may be pregnant, ask your doctor or pharmacist before taking any medicine.

TACROLIMUS MEDIS is excreted in breast milk and therefore you do not breast-feed while taking TACROLIMUS MEDIS.
Ask your doctor or pharmacist before taking any medicine.

Sports:
Not applicable.

Driving and using machines:
It is not advisable to drive or operate any tools or machines if you feel dizzy or if you feel sleepy (e), or if you have problems seeing clearly after taking TACROLIMUS MEDIS. These effects are most frequently observed when TACROLIMUS MEDIS is taken together with alcohol.

Important information about some components TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG:

TACROLIMUS MEDIS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3- HOW TO USE TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG ?

Always follow the dosage TACROLIMUS MEDIS indicated by your doctor. If in doubt, consult your doctor or pharmacist.

Make sure you get the same drug, tacrolimus whenever you receive your outlet unless your transplant specialist has agreed to change to another drug, tacrolimus. This medication should be taken twice daily. If the appearance of this drug is not the same as usual, or if dosage instructions have changed, tell your doctor or pharmacist to make sure you have the right medication immediately.

The loading dose to prevent rejection of your transplanted organ will be determined by your doctor calculated based on body weight. Initial doses immediately after transplantation are generally on the order of 0.075 to 0.30 mg per kg of body weight per day; the dose is set according to the transplanted organ.

Your dosage depends on your condition and other immunosuppressive medications you are taking.

Your doctor will do regular blood tests to determine the correct dose and dosage adjusted periodically. Usually, your doctor will lower the dose of TACROLIMUS MEDIS once your condition has stabilized. It will tell you exactly how many capsules to take and how often.

Posology and mode of administration :

- TACROLIMUS MEDIS be taken orally twice a day, usually in the morning and evening.

- In general, TACROLIMUS MEDIS should be taken at fasting (empty stomach) or at least 1 hour before 2 to 3 hours after a meal.

- The capsules should be swallowed whole with a glass of water.

- Take the capsules immediately following removal from the blister.

- Avoid consuming grapefruit or grapefruit juice during treatment with TACROLIMUS MEDIS.

If you have used more TACROLIMUS MEDIS that you should:
If you accidentally take too much TACROLIMUS MEDIS, consult your doctor or contact the emergency room of the nearest hospital immediately.

If you stop using TACROLIMUS MEDIS:
Never take a double dose to make up for the dose that you missed.
If you forget to take your capsules TACROLIMUS MEDIS, wait time for the next dose and continue taking doses as before.
Risk of withdrawal syndrome
The discontinuation of TACROLIMUS MEDIS may increase the risk of rejection of your transplanted organ. Therefore, you should never stop treatment unless your doctor tells you.
If you have questions about using this medicine, ask your doctor or pharmacist.

### 4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

Like all medicines, TACROLIMUS MEDIS may cause side effects, although not everybody will not matter.
TACROLIMUS MEDIS decreases defense mechanisms of your body to prevent you rejecting your transplanted organ. Therefore, your body will not be as effective as usual to fight against infections. So if you take TACROLIMUS MEDIS, you are likely to develop more infections such as infections of the skin, mouth, stomach and intestine, lung and urinary infections.
Severe reactions have been reported, including allergic and anaphylactic reactions. Tumors, both benign and malignant, resulting from immunosuppression, were observed after treatment with Tacrolimus.

Possible side effects are classified into the following categories: Very common side effects are seen in more than one in ten patients; Common side effects occurred in less than one in ten patients, but more than a hundred patients; Uncommon side effects occurred in less than one patient in a hundred but over a thousand patients; Rare side effects occurred in less than one patient in a thousand, but more than one patient in ten thousand; Very rare side effects occurred in less than one patient in ten thousand.

Very common side effects:
- increased levels of blood sugar, diabetes mellitus, increased levels of potassium in the blood;
- insomnia;
- tremor, headache;
- hypertension;
- diarrhea, nausea;
- kidney problems.

Common side effects:
- decrease the number of blood cells (platelets, red or white blood cells), increased white blood cell count, change in the number of red blood cells;
- decreased blood levels of magnesium, phosphate, potassium, calcium or sodium, fluid overload, increased uric acid or lipids in the blood, decreased appetite, increased acidity in the blood, other changes minerals in the blood;
- signs of anxiety, confusion and disorientation, depression, mood changes, nightmares, hallucinations, mental disorders;
- seizures, impaired consciousness, tingling and numbness (sometimes painful) in the hands and feet, dizziness, difficulty writing, nervous disorders;
- blurred vision, increased sensitivity to light, eye disorders;
- tinging in the ears;
- decreased blood flow in the vessels of the heart, increased heart rate;
- bleeding, partial or complete obstruction of blood vessels, lower blood pressure;
- shortness of breath, lung tissue changes, accumulation of fluid around the lungs, inflammation of the pharynx, cough, flu-like illness;
- inflammation or ulcers causing abdominal pain or diarrhea, stomach bleeding, inflammation or ulcers in the mouth, fluid accumulation in the abdomen, vomiting, abdominal pain, indigestion, constipation, gas, bloating, loose stools, difficulty stomach;
- abnormal liver enzymes and liver function, yellowing of the skin due to liver problems, damage to the liver tissue and liver inflammation;
- itching, rashes, hair loss, acne, excessive sweating;
- pain in the joints, limbs or back, muscle cramps;
- impairment of kidney function, decreased urine output, discomfort or pain on urination;
- general weakness, fever, fluid in your body, pain and discomfort, increased alkaline phosphatase enzyme in the blood, weight gain, impaired perception of temperature;
- Insufficient function of your transplanted organ.

Uncommon side effects:
- coagulation abnormalities, decreased number of all blood cells;
- dehydration, decreased levels of proteins or blood sugar, increase the levels of phosphate in the blood;
- coma, cerebral hemorrhage, stroke, paralysis, brain disorders, slurred speech and language, memory problems;
- lens opacity;
- hearing impairment;
- irregular heart beat, heart failure, decreased functioning of your heart, heart muscle disease, enlargement of the heart, increased heart rate, ECG abnormalities, abnormal pulse and heart rate;
- blood clot in a vein of a limb, vascular shock;
- difficulty breathing, respiratory tract disorders, asthma;
- bowel obstruction, increased enzyme levels in the blood amylase, reflux of stomach contents into the groove, delayed gastric emptying;
- dermatitis, burning sun;
- joint disorders;
- inability to urinate, painful menstruation and abnormal menstrual bleeding;
- failure of organs, flu-like illness, increased sensitivity to heat and cold, tightness in the chest, feeling jittery, feeling of not being in its normal state, increased enzyme lactate dehydrogenase in the blood, weight loss.

Rare side effects:
- small cutaneous bleeding caused by blood clots;
- increased muscle stiffness;
- blindness; deafness;
- accumulation of fluid around the heart; Acute respiratory difficulties;
- cyst formation in your pancreas; disorders of blood flow in the liver;
- serious illness with blistering of the skin, in the mouth, the eyes and genitals; excessive growth of hair;
- thirst, falls, tightness in your chest, decreased mobility, ulcer.

Very rare side effects:
- muscle weakness;
- abnormal echocardiogram;
- liver failure, narrowing of the bile ducts;
- painful urination with blood in the urine;
- increase in body fat.

If you notice any side effects not listed in this leaflet, or if the side effects gets serious, please tell your doctor or pharmacist.

### 5. HOW TO STORE TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG ?

No special precautions storage regarding temperature.
Store in the original container, away from moisture.

### 6. FURTHER INFORMATION :

What contain TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG:

| Actif ingredient : | TACROLIMUS MEDIS 1 MG | TACROLIMUS MEDIS 5 MG |
|---|---|---|
| Tacrolimus | 1mg | 5mg |
| Excipients : | Hydroxypropylmethylcellulose ; Lactose monohydrate ; Lactose anhydre ; Croscarmellose sodium ; Stearate magnesium. | |
| List of active excipients : | Lactose | |

What TACROLIMUS MEDIS 1 MG - TACROLIMUS MEDIS 5 MG, contents of the pack and M.A. number :
TACROLIMUS MEDIS 1 mg – I.N.N. : Tacrolimus – capsule – box of 100 capsules – M.A. N° : 923 371 1 H

TACROLIMUS MEDIS 5 mg – I.N.N. : Tacrolimus – capsule – box of 100 capsules – M.A. N° : 923 371 2 H

Authorization Holder of the marketing and manufacturer:

Marketing authorization holder and manufacturer: Laboratories MEDIS - Tunis road Km 7 - BP106 - 8000 Nabeul.

Manufacturer: Les Laboratoires MEDIS - Tunis road Km 7 - BP106 - 8000 Nabeul.

The last date on which this leaflet was last approved in:
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**THIS IS A DRUG**

- A drug is a product but not like the others.
- A drug is a product that is on your health and its non-conformity with the requirements consumption exposes you to danger.

- Follow strictly the doctor's prescription and the instructions that tells you to follow the advice of your pharmacist.
- Your doctor and pharmacist know about the drug, its indications and cons-indications.
- Do not stop your own treatment during the prescribed period.
- Do not pick up, do not increase the dose without consulting your doctor.

**Keep drugs out of the reach of children.**

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