

# TRANSGRAF

Tacrolimus Capsule (0.5 mg, 1 mg, 5 mg)

## What is in this leaflet

1. What *Transgraf* is used for
2. How *Transgraf* works
3. Before you use *Transgraf*
4. How to use *Transgraf*
5. While you are using *Transgraf*
6. Side effects
7. Storage and disposal of *Transgraf*
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision

## WHAT TRANSGRAF IS USED FOR

*Transgraf* is used to control your body's immune response enabling your body to accept the transplanted liver or kidney.

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

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

## HOW TRANSGRAF WORKS

*Transgraf* capsules contain the active ingredient Tacrolimus, which is a type of medicine called an immunosuppressant. Immunosuppressants are used to dampen down the activity of cells in the immune system.

## BEFORE YOU USE TRANSGRAF

### -When you must not use it

- If you are allergic (hypersensitive) to *Transgraf* or any of the other ingredients of *Transgraf*
- If you are allergic (hypersensitive) to any antibiotic belonging to the subgroup of macrolide antibiotics (e.g. erythromycin, clarithromycin, josamycin).

### Pregnancy and breast-feeding

If you plan to become pregnant or think that you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

-*Transgraf* is excreted into breast milk. Therefore, you should not breast-feed whilst receiving *Transgraf*.

-If you plan to become pregnant or think that you may be pregnant, ask your doctor

or pharmacist for advice before taking any medicine.

- *Transgraf* contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### -Before you start to use it

- You will need to take *Transgraf* every day as long as you need immunosuppression to prevent rejection of your transplanted organ. You should keep in regular contact with your doctor.

- Whilst you are taking *Transgraf* 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 *Transgraf* for you.

- Please avoid taking any herbal remedies, e.g. St. John's wort (*Hypericum perforatum*) or any other herbal products as this may affect the effectiveness and the dose of *Transgraf* that you need to receive. If in doubt, please consult your doctor prior to taking any herbal products or remedies.

- 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 *Transgraf* that you receive.

- If you have diarrhoea for more than one day, please tell your doctor, because it might be necessary to adapt the dose of *Transgraf* that you receive.

- If you need to have any vaccinations, please inform your doctor beforehand. Your doctor will advise you on the best course of action.

- Grapefruit and grapefruit juice should be avoided while taking *Transgraf*

### -Taking other medicines

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

*Transgraf* must not be taken with ciclosporin.

*Transgraf* blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking *Transgraf* which may require an increase or decrease in *Transgraf* dose. In particular, you should tell your doctor if you are taking or have recently taken medicines with active substances like:

- antifungal medicines and antibiotics (particularly so-called macrolide antibiotics) used to treat infections e.g. ketoconazole, fluconazole, itraconazole, voriconazole, clotrimazole, erythromycin, clarithromycin, josamycin, and rifampicin
- HIV protease inhibitors e.g. ritonavir
- omeprazole or lansoprazole, used for treating stomach ulcers
- 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
- medicines known as "statins" used to treat elevated cholesterol and triglycerides
- the anti-epileptic medicines phenytoin or phenobarbital
- the corticosteroids prednisolone and methylprednisolone
- the anti-depressant nefazodone
- St. John's Wort (*hypericum perforatum*)

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 *Transgraf*.

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), anticoagulants, or oral medication for diabetic treatment, while you take *Transgraf*.

If you need to have any vaccinations, please inform your doctor beforehand.

## HOW TO USE TRANSGRAF

### -How much to use

Always take *Transgraf* 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 *Transgraf* medicine every time you collect your prescription, unless your transplant

# TRANSGRAF

Tacrolimus Capsule (0.5 mg, 1 mg, 5 mg)

specialist has agreed to change to a different *Transgraf* medicine.

This medicine should be taken twice a day. If the appearance of this medicine is not the same as usual, or if dosage instructions have changed, speak to your doctor or pharmacist as soon as possible to make sure that you have the right medicine.

The starting dose to prevent the rejection of your transplanted organ will be determined by your doctor calculated according to your body weight. Initial doses just after transplantation will generally be in the range of 0.075 – 0.30 mg per kg body weight per day depending on the transplanted organ. 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

*Transgraf* dose once your condition has stabilised. Your doctor will tell you exactly how many capsules to take and how often. *Transgraf* is taken orally twice daily, usually in the morning and evening. You should generally take *Transgraf* on an empty stomach or at least 1 hour before or 2 to 3 hours after the meal. The capsules should be swallowed whole with a glass of water. Take the capsules immediately following removal from the blister. Avoid grapefruit and grapefruit juice while taking *Transgraf*. Do not swallow the desiccant contained in the foil wrapper.

Do not stop your treatment unless your doctor tells you to do so.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### -When to use it

Follow the instruction of your doctor or pharmacist.

### -How long to use it

Continue this medicine for time period set by your doctor.

### -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 *Transgraf* capsules, wait until it is time for the next dose, and then continue as before.

### -If you use too much

If you have accidentally taken too much *Transgraf* see your doctor or contact your nearest hospital emergency department immediately.

## **WHILE YOU ARE USING TRANSGRAF**

### -Things you must do

Tell your doctor if you become pregnant while taking *TRANSGRAF*

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking *TRANSGRAF*.

*TRANSGRAF* suppress your immune system by lowering your body's immune defense system. This increases your risk of skin cancer and other cancers while taking *TRANSGRAF*. Always protect yourself from the sun, wear sunscreen, a hat and protective clothing.

- Your doctor may need to conduct tests on you from time to time. This is important and will help your doctor to determine the most dosage suitable for you

### -Things you must not do

-Do not take *TRANSGRAF* to treat any other complaint unless your doctor says so.

-Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Do not stop using medicines this is unless directed by the doctor you.

- Stop your treatment with *Transgraf* can increase risk denial of your transfer organ.

- Do not start taking any new drug without talking with your doctor or pharmacist.

### -Things to be careful of

#### *Driving and using machines*

Do not drive or use any tools or machines if you feel dizzy or sleepy, or have problems seeing clearly after taking *Transgraf*. These effects are more frequently observed if *Transgraf* is taken in conjunction with alcohol use.

## **SIDE EFFECTS**

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

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

Severe effects have been reported, including allergic and anaphylactic reactions. Benign and malignant tumours have been reported following *Transgraf* treatment because of immunosuppression. Possible side effects are listed according to the following categories:

Very common side effects are experienced in more than one in ten patients.

Common side effects are experienced in less than one in ten patients but in more than one per one hundred patients.

Uncommon side effects are experienced in less than one in one hundred patients but more than one per one thousand patients.

Rare side effects are experienced in less than one per one thousand patients but more than one per ten thousand patients.

Very rare side effects are experienced in less than one per ten thousand patients.

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:

- Reduction in blood cell counts (platelets, red or white blood cells), increase in white blood cell counts, changes in red blood cell counts

- 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 salts

- Anxiety symptoms, confusion and disorientation, depression, mood changes, nightmare, hallucination, mental disorders

# TRANSGRAF

Tacrolimus Capsule (0.5 mg, 1 mg, 5 mg)

- 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
  - Shortness in breath, changes in the lung tissue, collection of liquid around the lung, inflammation of the pharynx, cough, flu-like symptoms
  - Inflammations or ulcers causing abdominal pain or diarrhoea, bleeds in the stomach, inflammations or ulcers in the mouth, collection of fluid in the belly, vomiting, abdominal pains, indigestion, constipation, flatulence, 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 or back, muscle cramps
  - 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, feeling of temperature disturbed
  - Insufficient function of your transplanted organ
- Uncommon side effects:
- Changes in blood clotting, reduction in all blood cell counts
  - Dehydration, reduced protein or sugar in the blood, increased phosphate in the blood
  - Coma, bleeding in the brain, stroke, paralysis, brain disorder, speech and language abnormalities, memory problems
  - Blurring of the vision due to abnormality in the lens of the eye
  - Impaired hearing

- Irregular heartbeat, stop of heartbeat, reduced performance of your heart, disorder of the heart muscle, enlargement of the heart muscle, stronger heartbeat, abnormal ECG, heart rate and pulse abnormal
- Blood clot in a vein of a limb, shock
- Difficulties in breathing, respiratory tract disorders, asthma
- Obstruction of the gut, increased blood level of the enzyme amylase, reflux of stomach content in your throat, delayed emptying of the stomach
- Dermatitis, burning sensation in the sunlight
- Joint disorders
- Inability to urinate, painful menstruation and abnormal menstrual bleeding
- Failure of some organs, influenza like illness, increased sensitivity to heat and cold, feeling of pressure on your chest, jittery or abnormal feeling, increase of the enzyme lactate dehydrogenase in your blood, weight loss

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

## STORAGE AND DISPOSAL OF TRANSGRAF

### Storage

Keep out of the reach and sight of children. Take the hard capsules immediately following removal from the blister. This medicinal product should be store below 30°C, in dry place. Protect from light.

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## PRODUCT DESCRIPTION

### -What Transgraf looks like

#### *Transgraf 0.5 mg hard capsules*

White to off white powder filled in size “5” yellow coloured cap/yellow coloured

body hard gelatin capsules printed with “0.5 mg” on cap and “Tacro” on body with red ink.

*Transgraf 0.5 mg hard capsules* are supplied as 5 or 10 blister strips with each blister strips containing 10 capsules and sealed in an aluminium wrapper.

#### *Transgraf 1.0 mg hard capsules*

White to off white powder filled in size “5” white coloured cap/white coloured body hard gelatin capsules printed with “1 mg” on cap and “Tacro” on body with red ink.

*Transgraf 1 mg hard capsules* are supplied as 5 or 10 blister strips with each blister strips containing 10 capsules and sealed in an aluminium wrapper

#### *Transgraf 5.0 mg hard capsules*

White to off white powder filled in size “4” grayish red coloured cap / grayish red coloured body hard gelatin capsules printed with “5mg” on cap and “Tacro” on body with white ink.

*Transgraf 5mg hard capsules* are supplied as 5 or 10 blister strips with each blister strips containing 10 capsules and sealed in an aluminium wrapper

## Ingredients

### *Transgraf 0.5 mg hard capsules*

- *Active Ingredient:* Each capsule contains 0.5 mg of Tacrolimus as Tacrolimus Monohydrate.

- *Inactive ingredients:* Capsule content: Hypromellose, croscarmellose sodium, lactose monohydrate, magnesium stearate. Capsule shell: Titanium dioxide, iron oxide yellow

### *Transgraf 1.0 mg hard capsules*

- *Active Ingredient:* Tacrolimus. Each capsule contains 1.0 mg of Tacrolimus as Tacrolimus Monohydrate.

- *Inactive ingredients:* Capsule content: Hypromellose, croscarmellose sodium, lactose monohydrate, magnesium Stearate. Capsule shell: Titanium dioxide.

### *Transgraf 5 mg hard capsules*

- *Active Ingredient:* Tacrolimus Each capsule contains 5 mg of Tacrolimus as Tacrolimus Monohydrate.

- *Inactive ingredients:* Capsule content: Hypromellose, croscarmellose sodium,

# TRANSGRAF

Tacrolimus Capsule (0.5 mg, 1 mg, 5 mg)

---

lactose monohydrate, magnesium Stearate. Capsule shell: Titanium dioxide, red iron oxide.

**-MAL Number:**

--Transgraf Capsule 0.5mg

MAL18071001AZ

--Transgraf Capsule 1mg

MAL18071002AZ

--Transgraf Capsule 5mg

MAL18071003AZ

**MANUFACTURER**

Alkem Laboratories Ltd. Village Thana,  
Solan District, Baddi, Himachal Pradesh,  
173 205, INDIA

H.O: ALKEM HOUSE, Senapati Bapat  
Marg, Lower Parel, Mumbai 400 013,  
India

**PRODUCT                      REGISTRATION**

**HOLDER**

Ascend Laboratories Sdn Bhd  
Level 25, Menara Hong Leong, No. 6,  
Jalan Damanlela, 50490 Bukit  
Damansara, Wilayah Persekutuan Kuala  
Lumpur, Malaysia

**DATE OF REVISION**

26/06/2019

**Serial number**

NPRA(R2/1)190625/177