PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TEVLIGRAF 0,5 (Prolonged-release hard capsule)

TEVLIGRAF 1 (Prolonged-release hard capsule)

TEVLIGRAF 3 (Prolonged-release hard capsule)

TEVLIGRAF 5 (Prolonged-release hard capsule)

Tacrolimus (as monohydrate)

TEVLIGRAF 0,5 contains sugar (lactose monohydrate 53,725 mg per prolonged-release hard capsule)
TEVLIGRAF 1 contains sugar (lactose monohydrate 107,45 mg per prolonged-release hard capsule)
TEVLIGRAF 3 contains sugar (lactose monohydrate 322,35 mg per prolonged-release hard capsule)
TEVLIGRAF 5 contains sugar (lactose monohydrate 537,25 mg per prolonged-release hard capsule)

Read all of this leaflet carefully before you start taking TEVLIGRAF.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEVLIGRAF has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What TEVLIGRAF is and what it is used for.

2. What you need to know before you take TEVLIGRAF.

3. How to take TEVLIGRAF.

4. Possible side effects.

5. How to store TEVLIGRAF.

6. Contents of the pack and other information.

1. What TEVLIGRAF is and what it is used for:

TEVLIGRAF is an immunosuppressant. Following your kidney liver or heart transplant, your body's immune system will try to reject the new organ. TEVLIGRAF is used to control your body's immune response, enabling your body to accept the transplanted organ.

You may also be given TEVLIGRAF for an ongoing rejection of your transplanted organ when the previous treatment you were taking was unable to control this immune response after your transplantation.

TEVLIGRAF is used in adults.

2. What you need to know before you take TEVLIGRAF:

Do not take TEVLIGRAF:

- If you are allergic (hypersensitive) to tacrolimus or any of the other ingredients of TEVLIGRAF (listed in **section 6**).
- If you are allergic to any macrolide antibiotic (e.g. clarithromycin, erythromycin, josamycin).
- If you are pregnant or breastfeeding (see **section 4.6**).
- If you are taking the oral contraceptive pill, TEVLIGRAF may change how it works. Other forms of contraception should be used e.g. condoms (see **Other medicines and TEVLIGRAF**).

- With live attenuated vaccines.

Warnings and precautions:

Take special care with TEVLIGRAF:

TEVLIGRAF contains the active substance tacrolimus presented in a prolonged-release formulation (delivers the dose over an extended period). TEVLIGRAF is taken once daily and is not interchangeable with other existing medicines containing tacrolimus (immediate release formulations).

Tell your doctor if any of the following apply to you:

- If you are taking any medicines mentioned below under **Other medicines and TEVLIGRAF**.
- If you need to be vaccinated.
- 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.
- If you have an alteration of the electrical activity of your heart called QT-prolongation.
- If you experience symptoms like headache, change in behaviour, seizures (body shakes rapidly and uncontrollably) and blurred or disturbed vision.
- If you have or have had liver problems.

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 TEVLIGRAF that you need to receive. If in doubt please consult your doctor prior to taking any herbal products or remedies.

Your doctor may need to adjust your dose of TEVLIGRAF.

You should limit your exposure to the sun and UV (ultraviolet) light whilst taking TEVLIGRAF. This is because immunosuppressants could increase the risk of skin cancer. Wear protective clothing and use a sunscreen with a high sun protection factor.

You should keep in regular contact with your doctor. From time to time, your doctor may need to do blood, urine, heart, or eye tests, to set the right dose of TEVLIGRAF.

Precaution for handling:

Direct contact with any part of your body like your skin or eyes, or breathing in of the powder contained in the capsules should be avoided. If such contact occurs, wash the skin and eyes.

Children and adolescents:

The use of TEVLIGRAF is not recommended in children and adolescents under 18 years.

Other medicines and TEVLIGRAF:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

TEVLIGRAF should not be taken with ciclosporin (another medicine used for the prevention of transplant organ rejection).

If you need to attend a doctor other than your transplant specialist, tell the doctor that you are taking TEVLIGRAF. Your doctor may need to consult your transplant specialist if you should use another medicine that could increase or decrease your tacrolimus blood level.

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

Some patients have experienced increases in tacrolimus blood levels while taking other medicines. This could lead to serious side effects, such as kidney problems, nervous system problems, and heart rhythm disturbances (see **section 4**).
An effect on the TEVLIGRAF blood levels may occur very soon after starting the use of another medicine, therefore frequent continued monitoring of your TEVLIGRAF blood level may be needed within the first few days of starting another medicine and frequently while treatment with the other medicine continues. Some other medicines may cause tacrolimus blood levels to decrease, which could increase the risk of rejecting the transplanted organ.
In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- antifungal medicines and antibiotics, particularly so-called macrolide antibiotics, used to treat infections e.g. ketoconazole, fluconazole, itraconazole, posaconazole, voriconazole, clotrimazole, isavuconazole, miconazole, telithromycin, erythromycin, clarithromycin, josamycin, azithromycin, rifampicin, rifabutin, isoniazid and flucloxacillin.
- letermovir, used to prevent illness caused by CMV (human cytomegalovirus).
- HIV protease inhibitors (e.g ritonavir, nelfinavir, saquinavir), the booster medicine cobicistat, and combination tablets, or HIV non-nucleoside reverse transcriptase inhibitors (efavirenz, etravirine, nevirapine), used to treat HIV infection.
- HCV protease inhibitors (e.g. telaprevir, boceprevir, the combination ombitasvir/paritaprevir/ritonavir with or without dasabuvir, elbasvir/grazoprevir, and glecaprevir/pibrentasvir), used to treat hepatitis C infection.

- nilotinib and imatinib, idelalisib, ceritinib, crizotinib, apalutamide, enzalutamide, or mitotane (used to treat certain cancers).
- mycophenolic acid, used to suppress the immune system to prevent transplant rejection.
- medicines for stomach ulcer and acid reflux (e.g omeprazole, lansoprazole, or cimetidine).
- antiemetics, used to treat nausea and vomiting (e.g. metoclopramide).
- cisapride or the antacid magnesium-aluminium-hydroxide, used to treat heartburn.
- nefazodone, used to treat depression.
- medicines used to treat high blood pressure or heart problems (e.g. nifedipine, nicardipine, diltiazem and verapamil).
- anti-dysrhythmic medicines (amiodarone) used to control dysrhythmia (uneven beating of the heart).
- medicines known as statins used to treat elevated cholesterol and triglycerides.
- ergotamine, used to relieve migraine headaches.
- herbal preparations containing St. John's wort (*Hypericum perforatum*) or extracts of *Schisandra sphenanthera*.
- carbamazepine, phenytoin or phenobarbital, used to treat epilepsy.
- the contraceptive pill or other hormone treatments with ethinylestradiol, hormone treatments with danazol.
- metamizole, used to treat pain and fever.
- the corticosteroids prednisolone and methylprednisolone, belonging to the class of corticosteroids used to treat inflammations or suppress the immune system (e.g. in transplant rejection).
- if you need to have any vaccinations, please tell your doctor before, because the vaccines may be less effective.
- cannabidiol (uses amongst others include treatment of seizures).

Tell your doctor if you are receiving treatment for hepatitis C. The medicine treatment for hepatitis C may change your liver function and may affect blood levels of tacrolimus. Tacrolimus blood levels may fall or may increase depending on the medicines prescribed for hepatitis C. Your doctor may need to closely monitor tacrolimus blood levels and make necessary adjustments of TEVLIGRAF dose after you start treatment for hepatitis C.

Tell your doctor if you are taking or need to take ibuprofen (used to treat fever, inflammation and pain), antibiotics (cotrimoxazole, vancomycin, or aminoglycoside antibiotics such as gentamicin), amphotericin B (used to treat fungal infections) or antivirals (used to treat viral infections, e.g. acyclovir, ganciclovir, cidofovir, foscarnet). These may worsen kidney or nervous system problems when taken together with TEVLIGRAF.

Your doctor also needs to know if you are taking potassium supplements or certain diuretics used for heart failure, hypertension and kidney disease, (e.g. amiloride, triamterene, or spironolactone), or the antibiotics trimethoprim or cotrimoxazole that may increase levels of potassium in your blood, nonsteroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) used for fever, inflammation and pain, anticoagulants (blood thinners), or oral medicines for diabetes, while you take TEVLIGRAF.

TEVLIGRAF with food and drink:
Avoid grapefruit (also as juice) while on treatment with TEVLIGRAF since it can affect its levels in the blood.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TEVLIGRAF.

Tacrolimus crosses the placenta. Do not take TEVLIGRAF during pregnancy.

TEVLIGRAF passes into breast milk. You should not breastfeed your baby whilst taking TEVLIGRAF.

Driving and using machines:

You may feel dizzy or sleepy, or have problems seeing clearly after taking TEVLIGRAF. These effects are more frequent if you also drink alcohol.

It is not always possible to predict to what extent TEVLIGRAF may interfere with your daily activities. You should not drive a vehicle or use machines until you are aware of the measure to which TEVLIGRAF affects you.

Important information about some of the ingredients of TEVLIGRAF:

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

TEVLIGRAF 5 mg capsules contains ponceau 4R. This may cause allergic reactions.

3. How to take TEVLIGRAF

Do not share medicines prescribed for you with any other person.

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

TEVLIGRAF should only be prescribed for you by a doctor with experience in the treatment of transplant patients.

Make sure that you receive the same tacrolimus (TEVLIGRAF) medicine every time you collect your prescription, unless your transplant specialist has agreed to change to a different tacrolimus medicine. If the appearance of the 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 daily doses just after transplantation will generally be in the range of 0,10 to 0,30 mg per kg body weight per day depending on the transplanted organ. When treating rejection, these same doses may be used.

Your dose depends on your general condition and on which other immunosuppressive medicines you are taking. Following the initiation of your treatment with TEVLIGRAF, frequent blood tests will be taken by your doctor to define the correct dose. Afterwards regular blood tests by your doctor will be required to define the correct dose and to adjust the dose from time to time.

TEVLIGRAF is taken orally once daily in the morning. Take TEVLIGRAF on an empty stomach or 2 to 3 hours after a meal. Wait at least 1 hour until the next meal. Take the capsules immediately following removal from the blister. The capsules should be swallowed whole with a glass of water. Do not swallow the desiccant contained in the foil wrapper.

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

If you take more TEVLIGRAF than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TEVLIGRAF:

If you have forgotten to take your TEVLIGRAF capsules in the morning, take them as soon as possible on the same day. Do not take double dose to make up for forgotten individual doses.

If you stop taking TEVLIGRAF:

Stopping your treatment with TEVLIGRAF may increase the risk of rejection of your transplanted organ. Do not stop your treatment unless your doctor tells you to do so.

4. Possible side effects:

TEVLIGRAF can have side effects.

Not all side effects reported for TEVLIGRAF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEVLIGRAF, please consult your healthcare provider for advice.

TEVLIGRAF reduces your body's defence mechanism (immune system), which will not be as good at fighting infections. Therefore, you may be more prone to infections while you are taking TEVLIGRAF.

Some infections could be serious or fatal and may include infections caused by bacteria, viruses, fungi, parasites, or other infections.

Tell your doctor immediately if you get signs of an infection including:

- Fever, cough, sore throat, feeling weak or generally unwell.
- Memory loss, trouble thinking, difficulty walking or loss of vision - these may be due to a less frequent, serious brain infection, which can be fatal (Progressive Multifocal Leukoencephalopathy or PML).

Severe effects may occur, including allergic and anaphylactic reactions. Benign and malignant tumours have been reported following TEVLIGRAF treatment.

If any of the following happens, stop taking TEVLIGRAF and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVLIGRAF. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you have or suspect you may have any of the following serious side effects:

Serious frequent side effects:

- Gastrointestinal perforation: strong abdominal pain accompanied or not with other symptoms, such as chills, fever, nausea or vomiting.
- Insufficient function of your transplanted organ.
- Blurred vision.

Serious less frequent side effects:

- Haemolytic uraemic syndrome, a condition with the following symptoms: low or no urine output (acute renal failure), extreme tiredness, yellowing of the skin or eyes (jaundice) and abnormal bruising or bleeding and signs of infection.
- Thrombotic Thrombocytopenic Purpura (or TTP) a condition characterised by fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice), with symptoms of acute renal failure (low or no urine output).

- Toxic epidermal necrolysis: erosion and blistering of skin or mucous membranes, red swollen skin that can detach in large parts of the body.
- Blindness.
- Stevens-Johnson syndrome: unexplained widespread skin pain, facial swelling, serious illness with blistering of skin, mouth, eyes and genitals, hives, tongue swelling, red or purple skin rash that spreads, skin shedding.
- *Torsades de Pointes*: change in the heart frequency that can be accompanied or not of symptoms, such as chest pain (angina), faint, vertigo or nausea, palpitations (feeling the heartbeat) and difficulty breathing.

Serious side effects - frequency is unknown:

- Opportunistic infections (bacterial, fungal, viral and protozoal): prolonged diarrhoea, fever and sore throat.
- Benign and malignant tumours have been reported following treatment as a result of immunosuppression.
- Cases of pure red cell aplasia (a very severe reduction in red blood cell counts), haemolytic anaemia (decreased number of red blood cells due to abnormal breakdown accompanied with tiredness) and febrile neutropenia (a decrease in the type of white blood cells which fight infection, accompanied by fever) have been reported. It is not known exactly how often these side effects occur. You may have no symptoms or depending on the severity of the condition, you may feel: fatigue, apathy, abnormal paleness of the skin (pallor), shortness of breath, dizziness, headache, chest pain and coldness in hands and feet.
- Cases of agranulocytosis (a severely lowered number of white blood cells accompanied with ulcers in the mouth, fever and infections). You may have no symptoms or you may feel sudden fever, rigors and sore throat.

- Posterior Reversible Encephalopathy Syndrome (PRES): headache, confusion, mood changes, fits, and disturbances of your vision. These could be signs of a disorder known as posterior reversible encephalopathy syndrome, which has been reported in some patients treated with TEVLIGRAF.
- Optic neuropathy (abnormality of the optic nerve): problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or restriction of your field of vision.

These are all serious side effects. You may need urgent medical attention.

The side effects listed below may also occur after receiving TEVLIGRAF and could be serious:

Frequent side effects:

- increased blood sugar, diabetes mellitus, increased potassium in the blood
- difficulty in sleeping
- trembling, headache
- increased blood pressure
- liver function tests abnormal
- diarrhoea, nausea
- kidney problems
- reduction in blood cell counts (platelets, red or white blood cells), increase in white blood cell counts, changes in red blood cell counts (seen in blood tests)
- 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 (seen in blood tests)
- 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
- eye disorders, increased sensitivity to light
- 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 tissues, collection of liquid around the lung, inflammation of the pharynx, cough, flu-like symptoms
- inflammations or ulcers causing abdominal pain or diarrhoea, bleeding in the stomach
- inflammations or ulcers in the mouth, collection of fluid in the belly, vomiting
- abdominal pain, indigestion, constipation, flatulence, bloating, loose stools, stomach problems
- bile duct disorders, 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, feeling of temperature disturbed.

Less frequent side effects:

- changes in blood clotting, reduction in the number of all types of blood cells (seen in blood tests)

- 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
- increased hairiness
- psychotic disorder
- opacity of the eye lens
- 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
- cyst formation in your pancreas
- obstruction of the gut, increased blood level of the enzyme amylase
- reflux of stomach content in your throat, delayed emptying of the stomach
- problems with blood flow in the liver, liver failure
- inflammation of the skin, burning sensation in the sunlight
- serious illness with blistering of skin, mouth, eyes and genitals
- joint disorder, decreased mobility
- unable to pass urine
- painful urination with blood in the urine
- inability to urinate, painful menstruation and abnormal menstrual bleeding
- multiple organ failure, flu-like illness, increased sensitivity to heat and cold, feeling of pressure on your chest, jittery or abnormal feeling, weight loss
- increase of fat tissue
- increase of the enzyme lactate dehydrogenase

- small bleedings in your skin due to blood clots
- increased muscle stiffness
- deafness
- collection of fluid around the heart
- acute breathlessness
- thirst, fall, feeling of tightness in your chest, ulcer
- muscular weakness
- abnormal heart scan.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 By reporting side effects, you can help provide more information on the safety of TEVLIGRAF.

5. How to store TEVLIGRAF:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original package to protect from light and moisture.

Do not use after the expiry date stated on the blisters.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What TEVLIGRAF contains:

The active substance is tacrolimus (as monohydrate).

The other ingredients are:

Capsule content: Ethylcellulose, hypromellose (type 2910), lactose monohydrate, magnesium stearate.

Capsule shell: Black iron oxide (E172), gelatin, ponceau 4R, red iron oxide (E 172), yellow iron oxide (E 172), titanium dioxide (E171).

Printing ink: Black iron oxide, potassium hydroxide, propylene glycol and shellac.

What TEVLIGRAF looks like and contents of the pack:

TEVLIGRAF 0,5: Size 5 hard gelatin capsules filled with white to off-white powder. Body: light orange with “0.5 mg” radial black imprinting. Cap: light yellow with “TR” radial black imprinting.

TEVLIGRAF 1: Size 4 hard gelatin capsules filled with white to off-white powder. Body: light orange with “1 mg” radial black imprinting. Cap: White with “TR” radial black imprinting.

TEVLIGRAF 3: Size 1 hard gelatin capsules filled with white to off-white powder. Body: light orange with “3 mg” radial black imprinting. Cap: light orange with “TR” radial black imprinting.

TEVLIGRAF 5: Size 0 hard gelatin capsules filled with white to off-white powder. Body: light orange with “5 mg” radial black imprinting. Cap: greyish red with “TR” radial black imprinting.

TEVLIGRAF 0,5: Capsules are packed into PVC/PVdC-Aluminium blisters. Blisters are packed into a multilayer aluminium pouch with desiccant.

Packs of 30, 50 and 100 prolonged-release capsules are available.

TEVLIGRAF 1: Capsules are packed into PVC/PVdC-Aluminium blisters. Blisters are packed into a multilayer aluminium pouch with desiccant.

Packs of 30, 50, 60 and 100 prolonged-release capsules are available.

TEVLIGRAF 3: Capsules are packed into PVC/PVdC-Aluminium blisters. Blisters are packed into a multilayer aluminium pouch with desiccant.

Packs of 30, 50 and 100 prolonged-release capsules are available.

TEVLIGRAF 5: Capsules are packed into PVC/PVdC-Aluminium blisters. Blisters are packed into a multilayer aluminium pouch with desiccant.

Packs of 30, 50 and 100 prolonged-release capsules are available.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: (011) 055 0200

This leaflet was last revised in:

10 November 2022

Registration number:

TEVLIGRAF 0,5: 52/34/0220

TEVLIGRAF 1: 52/34/0221

TEVLIGRAF 3: 52/34/0222

TEVLIGRAF 5: 52/34/0223

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

TEVLIGRAF 0,5 (Verlengde-vrystellende harde kapsule)

TEVLIGRAF 1 (Verlengde-vrystellende harde kapsule)

TEVLIGRAF 3 (Verlengde-vrystellende harde kapsule)

TEVLIGRAF 5 (Verlengde-vrystellende harde kapsule)

Takrolimus (as monohidraat)

TEVLIGRAF 0,5 bevat suiker (laktosemonohidraat 53,725 mg per verlengde-vrystellende harde kapsule)
TEVLIGRAF 1 bevat suiker (laktosemonohidraat 107,45 mg per verlengde-vrystellende harde kapsule)
TEVLIGRAF 3 bevat suiker (laktosemonohidraat 332,35 mg per verlengde-vrystellende harde kapsule)
TEVLIGRAF 5 bevat suiker (laktosemonohidraat 537,25 mg per verlengde-vrystellende harde kapsule)

Lees hierdie hele blad noukeurig deur voordat u begin om TEVLIGRAF te drink.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- TEVLIGRAF is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is:

1. Wat TEVLIGRAF is en waarvoor dit gebruik word

2. Wat u moet weet voordat u TEVLIGRAF drink

3. Hoe om TEVLIGRAF te drink

4. Moontlike newe-effekte

5. Hoe om TEVLIGRAF te bêre

6. Inhoud van die pak en ander inligting

1. Wat TEVLIGRAF is en waarvoor dit gebruik word

TEVLIGRAF is ’n immuunonderdrukker. Ná u nier-, lewer- of hartoorplanting sal u liggaam se immuunstelsel probeer om die nuwe orgaan te verwerp. TEVLIGRAF word gebruik om u liggaam se immuunrespons te beheer, wat u liggaam in staat stel om die oorgeplante orgaan te aanvaar.

U kan TEVLIGRAF ook vir ’n voortdurende verwerping van u oorgeplante orgaan kry wanneer die vorige behandeling wat u gehad het nie in staat was om hierdie immuunrespons na u oorplanting te beheer nie.

TEVLIGRAF word vir volwassenes gebruik.

2. Wat u moet weet voordat u TEVLIGRAF drink:

Moenie TEVLIGRAF drink nie:

- as u allergies (hipersensitief) vir takrolimus of vir enige van die ander bestanddele van TEVLIGRAF (gelys in **afdeling 6**) is
- as u allergies vir enige makroliedantibiotikum (bv. klaritromisien, eritromisien, josamisien) is;
- as u swanger is of borsvoed (sien **afdeling 4.6**)

- as u die orale voorbehoedpil gebruik, kan TEVLIGRAF die manier waarop dit werk verander. Ander vorme van voorbehoedmiddels moet gebruik word, bv. kondome (sien **Ander medisyne en TEVLIGRAF**)
- as u met lewende verswakte entstowwe ingeënt word.

Waarskuwings en voorsorgmaatreëls:

Wees besonder versigtig met TEVLIGRAF:

TEVLIGRAF bevat die aktiewe bestanddeel takrolimus wat in ’n verlengde vrystellende formulering aangebied word (lewer die dosis oor ’n lang tydperk). TEVLIGRAF word een keer per dag gedrink en is nie uitruilbaar met ander bestaande medisyne wat takrolimus (onmiddellik-vrystellende formulerings) bevat nie.

Sê vir u dokter indien enige van die volgende op u van toepassing is:

- As u enige van die middels hier onder genoem, gebruik (sien **Ander medisyne en TEVLIGRAF**).
- As u ingeënt moet word.
- As u erge buikpyn voel met ander simptome al dan nie, soos kouekoors, koors, naarheid of braking.
- As u vir meer as een dag diarree het.
- As u ’n rekord van abnormale elektriese aktiwiteit van die hart het (verlenging van die QT-interval in die elektrokardiogram).
- As u simptome soos hoofpyn, verandering in gedrag, toevalle (liggaam skud vinnig en onbeheerbaar) en dowwe of versteurde visie ervaar.
- As u lewerprobleme het of voorheen gehad het.

Vermy die neem van enige kruiemiddels, bv. St. Janskruid (*Hypericum perforatum*) of enige ander kruieprodukte aangesien dit die doeltreffendheid van jou TEVLIGRAF dosiswat jy

ontvang kan beïnvloed. As u twyfel, raadpleeg u dokter voordat u enige kruieprodukte of -middels gebruik.
Jou dokter sal dalk jou TEVLIGRAF dosis moet aanpas.

U moet u blootstelling aan die son en UV- (ultraviolet) lig beperk terwyl u TEVLIGRAF drink. Dit is omdat immuunonderdrukkers die risiko vir velkanker kan verhoog. Dra beskermende klere en gebruik ’n sonskerm met ’n hoë sonbeskermingsfaktor.

Bly in gereelde kontak met jou dokter Van tyd tot tyd sal u dokter dalk bloed-, urien-, hart- of oogtoetse moet doen om die regte dosis TEVLIGRAF te gee.

Voorsorgmaatreëls vir hantering:
Direkte kontak met enige deel van jou liggaam soos jou vel of oë, of inasem van die poeier wat in die kapsules is, moet vermy word. Indien kontak voorkom moet die vel en oë gewas word.

Kinders en adolessente:
Die gebruik van TEVLIGRAF vir kinders jonger as 18 jaar word nie aanbeveel nie.

Ander medisyne en TEVLIGRAF:
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
TEVLIGRAF moet nie saam met siklosporien (’n ander middel vir die voorkoming van oorplantingorgaanverwerping) gebruik word nie.

As jy 'n ander dokter as jou oorplantingspesialis moet besoek, vertel die dokter dat jy TEVLIGRAF neem. Jou dokter sal dalk jou oorplantingspesialis moet raadpleeg as jy 'n ander medisyne moet gebruik wat jou takrolimus-bloedvlak kan verhoog of verlaag.

Die bloedvlakke van TEVLIGRAF kan beïnvloed word deur ander medisyne wat u gebruik, en bloedvlakke van ander medisyne kan deur TEVLIGRAF beïnvloed word, wat onderbreking, waarvoor ’n verhoging of verlaging in dosis van TEVLIGRAF nodig mag wees.

Sommige pasiënte het verhogings in takrolimus-bloedvlakke ervaar terwyl hulle ander medisyne geneem het. Dit kan lei tot ernstige newe-effekte, soos nierprobleme, senuweestelselprobleme en hartritmestoornisse (sien **afdeling 4**).
'n Effek op die TEVLIGRAF-bloedvlakke kan baie gou na die aanvang van die gebruik van 'n ander medisyne voorkom, daarom kan gereelde volgehoue monitering van u TEVLIGRAF-bloedvlak nodig wees binne die eerste paar dae na die aanvang van 'n ander medisyne en gereeld terwyl behandeling met die ander medisyne voortduur. Sommige ander medisyne kan die takrolimus-bloedvlakke laat daal, wat die risiko kan verhoog om die oorgeplante orgaan te verwerp. In besonder, moet jy jou dokter vertel as jy medisyne gebruik of onlangs geneem het soos:

- antifungus medisyne en antibiotika, veral sogenaamde makrolied-antibiotika, wat gebruik word om infeksies te behandel bv. ketokonasool, flukonasool, itrakonasool, posakonasool, vorikonasool, klotrimasool, isavukonasool, mikonasool, telitromisien, eritromisien, klaritromisien, josamisien, azitromisien, rifampisien, rifabutien, isoniazid en flukloksosien.
- letermovir, gebruik om siektes wat deur CMV (menslike sitomegalovirus) veroorsaak word, te voorkom.
- MIV-protease-inhibeerders (bv. ritonavir, nelfinavir, saquinavir), die boostermedisyne cobicistat, en kombinasietablette, of MIV-nie-nukleosied omgekeerde transkriptase-inhibeerders (efavirens, etravirien, nevirapien) wat gebruik word om MIV-infeksie te behandel.

- HCV-protease-inhibeerders (bv. telaprevir, boceprevir, die kombinasie ombitasvir/paritaprevir/ritonavir met of sonder dasabuvir, elbasvir/grazoprevir en glecaprevir/pibrentasvir), wat gebruik word om hepatitis C-infeksie te behandel.
- nilotinib en imatinib, idelalisib, ceritinib, crizotinib, apalutamide, enzalutamide of mitotaan (gebruik om sekere kankers te behandel).
- mikofenolsuur, wat gebruik word om die immuunstelsel te onderdruk om oorplantingverwerping te voorkom.
- medisyne vir maag ulkus en suur refluks (bv. omeprazol, lansoprazol of cimetidien).
- antiemetika, gebruik om naarheid en braking te behandel (bv. metoklopramied).
- cisapried of die teensuurmiddel magnesium-aluminium-hidroksied, wat gebruik word om sooibrand te behandel.
- nefazodoon, wat gebruik word om depressie te behandel.
- medisyne wat gebruik word om hoë bloeddruk of hartprobleme te behandel (bv. nifedipien, nikardipien, diltiazem en verapamil).
- anti-disritmiese medisyne (amiodaroon) wat gebruik word om disritmie te beheer (ongelyke klop van die hart).
- medisyne bekend as statiene wat gebruik word om verhoogde cholesterol en trigliseriede te behandel.
- ergotamien, wat gebruik word om migraine hoofpyne te verlig.
- kruiepreparate wat St. Janskruid (*Hypericum perforatum*) of ekstrakte van *Schisandra sphenanthera* bevat.
- karbamasepien, fenitoïen of fenobarbital, gebruik om epilepsie te behandel.
- die voorbehoedpil of ander hormoonbehandelings met etinielestradiol, hormoonbehandelings met danazol.
- metamizool, gebruik om pyn en koors te behandel.

- die kortikosteroïede prednisoloon en metielprednisoloon, wat aan die klas kortikosteroïede behoort wat gebruik word om inflammasie te behandel of die immuunstelsel te onderdruk (bv. in oorplantingverwerping).
- as jy enige inentings moet kry, vertel jou dokter vooraf, want die entstowwe kan minder doeltreffend wees.
- cannabidiol (gebruike sluit onder andere behandeling van aanvalle in)

Vertel jou dokter as jy behandeling vir hepatitis C ontvang. Die medisynebehandeling vir hepatitis C kan jou lewerfunksie verander en kan bloedvlakke van takrolimus beïnvloed. Takrolimus bloedvlakke kan daal of kan styg, afhangende van die medisyne wat vir hepatitis C voorgeskryf word. Jou dokter sal dalk takrolimus-bloedvlakke noukeurig moet monitor en die nodige aanpassings van die TEVLIGRAF dosis moet maak nadat jy met behandeling vir hepatitis C begin het.

Vertel jou dokter as jy ibuprofen (wat gebruik word om koors, inflammasie en pyn te behandel), antibiotika (kotrimoksasool, vankomisien of aminoglikosied antibiotika soos gentamisien), amfoterisien B (gebruik om swaminfeksies te behandel) of antivirale middels (gebruik) neem of moet neem vir die behandeling van virale infeksies, bv. acyclovir, ganciclovir, cidofovir, foscarnet). Dit kan nier- of senuweestelselprobleme vererger wanneer dit saam met TEVLIGRAF geneem word.

U dokter moet ook weet of u terwyl u TEVLIGRAF drink kaliumaanvullings of sekere diuretika vir hartversaking, hipertensie en niersiekte (bv. amiloried, triamterene of spironolaktoon) of die antibiotika trimetoprim of cotrimoxazole wat die vlakke van kalium in jou bloed kan verhoog, niesteroïed anti-inflammatoriese middels (NSAIM's, bv. ibuprofeen) vir koors, inflammasie en pyn, antikoagulante (bloeddunmakers), of orale medisyne vir diabetes.

TEVLIGRAF saam met voedsel en drank:

Vermy pomelo's (ook as sap) tydens behandeling met TEVLIGRAF aangesien dit die vlakke daarvan in die bloed kan beïnvloed.

Swangerskap en borsvoeding:

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u TEVLIGRAF drink.

Takrolimus kruis die plasenta. Moenie TEVLIGRAF tydens swangerskap gebruik nie.

TEVLIGRAF word in borsmelk uitgeskei. U moet nie u baba borsvoed terwyl u TEVLIGRAF drink nie.

Motorbestuur en gebruik van masjinerie:

U kan duiselig of lomerig voel, of probleme ondervind om helder te sien nadat u TEVLIGRAF gedrink het. Hierdie effekte kom meer dikwels voor as u ook alkohol drink.

Dit is nie altyd moontlik om te voorspel tot watter mate TEVLIGRAF met u daaglikse aktiwiteite kan inmeng nie. U moet sorg dat u nie 'n voertuig bestuur of masjiene hanteer nie, totdat u weet hoe TEVLIGRAF u beïnvloed.

Belangrike inligting oor sommige van die bestanddele van TEVLIGRAF:

TEVLIGRAF bevat laktose. As u dokter vir u gesê het dat u 'n onverdraagbaarheid vir sekere suikers het, moet u u dokter skakel voordat u TEVLIGRAF drink.

TEVLIGRAF 5 mg kapsules bevat ponceau 4R. Dit kan allergiese reaksies veroorsaak.

3. Hoe om TEVLIGRAF te drink:

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Drink TEVLIGRAF altyd presies soos wat u dokter vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
TEVLIGRAF moet slegs deur ’n dokter met ondervinding in die behandeling van oorplantingspasiënte aan u voorgeskryf word.
Maak seker dat u dieselfde takrolimusmedisyne (TEVLIGRAF) kry elke keer as u u voorskrif kry, tensy u oorplantingspesialis ingestem het om na ’n ander takrolimusmedisyne te verander. As die voorkoms van die medisyne nie soos gewoonlik is nie, of as die dosisinstruksies verander het, moet u so gou moontlik met u dokter of apteker praat om seker te maak dat u die regte medisyne het.
Die aanvangsdosis om die verwerping van u oorgeplante orgaan te voorkom, sal volgens u liggaamsgewig deur u dokter bepaal word. Aanvanklike daaglikse dosisse net na die oorplanting sal gewoonlik in die gebied van 0,10 tot 0,30 mg per kg liggaamsgewig per dag wees, afhangende van die oorgeplante orgaan. Wanneer verwerping behandel word, kan dieselfde dosisse gebruik word.
U dosis hang af van u algemene toestand en van watter ander immuunonderdrukkende medisyne u gebruik. Nadat u behandeling met TEVLIGRAF begin het, sal u dokter gereeld bloedtoetse doen om die korrekte dosis te bepaal. Daarna sal u dokter gereelde bloedtoetse nodig hê om die korrekte dosis te bepaal en om die dosis van tyd tot tyd aan te pas.
TEVLIGRAF word een keer per dag in die oggend gedrink. Drink TEVLIGRAF op ’n leë maag of 2 tot 3 uur na ’n ete. Laat ten minste 1 uur voor die volgende ete. Drink die kapsules onmiddellik nadat u dit uit die stulpstrook gehaal het. Die kapsule moet heel met ’n glas water afgesluk word. Moenie die droogmiddel wat in die foeliesakkie is, drink nie.
U moet TEVLIGRAF elke dag drink vir so lank as wat u immuunonderdrukking nodig het om verwerping van u oorgeplante orgaan te voorkom. Bly in gereelde kontak met jou dokter

As u meer TEVLIGRAF gedrink het as wat u moes:

Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om TEVLIGRAF te drink:

As u vergeet het om u TEVLIGRAF-kapsules in die oggend te drink, drink dit so gou moontlik op dieselfde dag. Moenie ’n dubbele dosis drink om vir vergete individuele dosisse op te maak nie.

As u ophou om TEVLIGRAF te drink:

As u u behandeling met TEVLIGRAF stop, kan u die kans vir die verwerping van u oorgeplante orgaan verhoog. Moenie ophou om TEVLIGRAF te drink tensy u dokter so sê nie.

4. Moontlike newe-effekte:

TEVLIGRAF kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir TEVLIGRAF aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u TEVLIGRAF drink, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.

TEVLIGRAF verlaag u liggaam se verdedigingsmeganisme (immuunstelsel), wat nie so goed sal werk om infeksies te beveg nie. Daarom kan u meer geneig wees om infeksies te kry terwyl u TEVLIGRAF drink.
Sommige infeksies kan ernstig of dodelik wees en kan infeksies insluit wat veroorsaak word deur bakterieë, virusse, swamme, parasiete of ander infeksies. Vertel jou dokter dadelik as jy tekens van 'n infeksie kry, insluitend:

- Koors, hoes, seer keel, voel swak of algemeen onwel.
- Geheueverlies, probleme om te dink, probleme om te loop of verlies van visie - dit kan wees as gevolg van 'n minder gereelde, ernstige breininfeksie, wat dodelik kan wees (Progressiewe Multifokale Leuko-enkefalopatie of PML).

Erge effekte kan voorkom, insluitend allergiese en anafilaktiese reaksies. Goedaardige en kwaadaardige gewasse is na TEVLIGRAF-behandeling aangemeld.

Indien enige van die volgende voorkom, moet u ophou om TEVLIGRAF te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u ’n ernstige reaksie op TEVLIGRAF gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy het of vermoed dat jy enige van die volgende ernstige newe-effekte kan hê:

Ernstige gereelde newe-effekte:

- Gastrointestinale perforasie: sterk buikpyn al dan nie vergesel met ander simptome, soos kouekoors, koors, naarheid of braking.
- Onvoldoende funksie van jou oorgeplante orgaan.
- Versteurde visie.

Ernstige minder gereelde newe-effekte:

- Hemolitiese uremiese sindroom, 'n toestand met die volgende simptome: lae of geen urienuitset (akute nierversaking), uiterste moegheid, vergeling van die vel of oë (geelsug) en abnormale kneusing of bloeding en tekens van infeksie.
- Trombotiese Trombositopeniese Purpura (of TTP), 'n toestand wat gekenmerk word deur koors en kneusing onder die vel wat as rooi puntpunte kan voorkom, met of

sonder onverklaarbare uiterste moegheid, verwarring, vergeling van die vel of oë (geelsug), met simptome van akute nier mislukking (lae of geen urine uitset).

- Giftige epidermale nekrolise: erosie en blase van vel of slymvliese, rooi geswelde vel wat in groot dele van die liggaam kan los raak.
- Blindheid.
- Stevens-Johnson-sindroom: onverklaarbare wydverspreide velpyn, gesigswelling, ernstige siekte met blase op die vel, mond, oë en geslagsdele, korwe, tongswelling, rooi of pers veluitslag wat versprei, velafskeiding.
- *Torsades de Pointes*: verandering in die hartfrekwensie wat al dan nie gepaard kan gaan met simptome, soos borspyn (angina), floutes, vertigo of naarheid, hartkloppings (voel die hartklop) en moeilike asemhaling.

Ernstige newe-effekte - frekwensie is onbekend:

- Opportunistiese infeksies (bakterieë, swam, virale en protosoë): langdurige diarree, koors en seer keel.
- Goedaardige en kwaadaardige gewasse is aangemeld na behandeling as gevolg van immuunonderdrukking.
- Gevalle van suiwer rooisel-aplasie ('n baie ernstige afname in rooibloedseltellings), hemolitiese anemie (verminderde aantal rooibloedselle as gevolg van abnormale afbreek gepaardgaande met moegheid) en febriele neutropenie ('n afname in die tipe witbloedselle wat infeksie te beveg, gepaardgaande met koors) is aangemeld. Dit is nie presies bekend hoe gereeld hierdie newe-effekte voorkom nie. Jy mag dalk geen simptome hê nie of afhangende van die erns van die toestand, kan jy voel: moegheid, apatie, abnormale bleekheid van die vel (bleekheid), kortasem, duiseligheid, hoofpyn, borspyn en koue in hande en voete.

- Gevalle van agranulositose ('n erge verlaagde aantal witbloedselle wat gepaard gaan met maagsere in die mond, koors en infeksies). Jy mag dalk geen simptome hê nie of jy kan skielike koors, erge en seer keel voel.
- Posterior omkeerbare enkefalopatie-sindroom (PRES): hoofpyn, verwarring, gemoedsveranderinge, aanvalle en versteurings van jou visie. Dit kan tekens wees van 'n versteuring bekend as posterior omkeerbare enkefalopatie-sindroom, wat by sommige pasiënte wat met TEVLIGRAF behandel is, aangemeld is.
- Optiese neuropatie (abnormaliteit van die optiese senuwee): probleme met jou visie soos versteurde visie, veranderinge in kleurvisie, moeilikheid om detail te sien of beperking van jou gesigsveld.

Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Die newe-effekte hieronder gelys kan ook voorkom na die neem van TEVLIGRAF en kan ernstig wees:

Algemene newe-effekte:

- verhoogde bloedsuiker, diabetes mellitus, verhoogde kalium in die bloed.
- moeilikheid om te slaap.
- bewing, hoofpyn
- verhoogde bloeddruk
- lewerfunksietoetse abnormaal
- diarree, naarheid
- nierprobleme
- daling in bloedseltellings (plaatjies, rooi- of witbloedselle), toename in witbloedseltellings, veranderinge in rooibloedseltellings (gesien in bloedtoetse)
- minder magnesium, fosfaat, kalium, kalsium of natrium in die bloed, vloeistofoorlading

- hoër vlakke uriensuur of lipiede in die bloed, laer eetlus, hoër suurheid van die bloed, ander veranderinge in die bloedsoute (gesien in bloedtoetse)
- angs simptome, verwarring en disoriëntasie, depressie, gemoedsveranderinge, nagmerrie, hallusinasies, geestesversteurings
- aanvalle, bewussynsversteurings, tinteling en gevoelloosheid (soms pynlik) in die hande en voete, duiseligheid, verswakte skryfvermoë, senuweestelselafwykings
- oogafwykings, groter sensitiwiteit vir lig
- gelui in die ore
- minder bloedvloei in die hartvate, vinniger hartklop
- bloeding, gedeeltelike of volledige blokkering van bloedvate, lae bloeddruk
- kortasemheid, veranderinge in die respiratoriese weefsel, versameling van vloeistof rondom die longe, ontsteking van die farinks, hoes, griepagtige simptome
- inflammasie of ulkusse wat buikpyn of diarree veroorsaak, bloeding in die maag
- inflammasies of sere in die mond, versameling van vloeistof in die maag, braking
- abdominale pyn, slegte spysvertering, hardlywigheid, winderigheid, opgeblasenheid, los stoelgang, maag probleme
- galafwykings, geel verkleuring van die vel as gevolg van lewerprobleme, skade aan lewerweefsel en inflammasie van die lewer
- jeuk, uitslag, haarverlies, aknee, meer sweet
- pyn in die gewrigte, ledemate, rug en voete
- spier spasmas
- onvoldoende funksie van die niere, minder produksie van urien, swak of pynlike urinering
- algemene swakheid, koors, versameling van vloeistof in die liggaam, pyn en ongemak
- toename van die ensiem alkaliese fosfatase in die bloed, gewigstoename, gevoel van versteurde temperatuur.

Minder algemene newe-effekte:

- veranderinge in bloedstolling, vermindering in die aantal van alle soorte bloedselle (gesien in bloedtoetse)
- dehidrasie
- verminderde proteïen of suiker in die bloed, verhoogde fosfaat in die bloed
- koma, bloeding in die brein, beroerte, verlamming, breinafwyking, spraak- en taalafwykings, geheueprobleme
- vermeerderde harigheid
- psigotiese versteurings
- ondeursigtigheid van die ooglens
- gestremde gehoor
- onreëlmatige hartklop, stop van hartklop, swakker werking van die hart
- versteuring van die hartspier, vergroting van die hartspier, sterker hartklop abnormale EKG, hartklop en pols abnormaal
- bloedklont in ’n aar van ’n ledemaat, skok
- probleme met asemhaling, lugwegafwykings, asma
- vorming van sist in die pankreas
- obstruksie in die ingewande, hoër vlakke van die ensiem amilase in die bloed
- refluks van maaginhoud in die keel, stadige lediging van die maag
- probleme met bloedvloei in die lewer, lewerversaking
- inflammasie van die vel, brandende sensasie in sonlig
- ernstige siekte met blase op die vel, mond, oë en geslagsdele
- gewrigsversteuring, minder mobiliteit
- onvermoë om te urineer
- pynlike urinering met bloed in die urien
- onvermoë om te urineer, pynlike menstruasie en abnormale menstruele bloeding

- meervoudige orgaanversaking, griepagtige siekte, hoër sensitiwiteit vir hitte en koue, gevoel van druk op die bors, wankelrige of abnormale gevoel, gewigsverlies
- toename in vetweefsel
- hoër vlakke van die ensiem laktaatdehidrogenase,
- klein bloeding onder jou vel as gevolg van bloedklonte
- verhoogde spierstyfheid
- doofheid
- versameling van vloeistof om die hart
- akute asemloosheid
- dors, val, gevoel van benoudheid in jou bors, ulkus
- spierswakheid
- abnormale hartskandering.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte:

Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SAROGP (SAHPRA) aanmeld met die toepaslike vorm, naamlik **6.04 Adverse Drug Reaction Reporting Form** wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TEVLIGRAF te gee.

5. Hoe om TEVLIGRAF te bêre:

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Bêre by of onder 25 °C.

Bêre in die oorspronklike pakkie om teen lig en vog te beskerm.

Moenie na die vervaldatum op die stulpstroke gebruik nie.

Gee alle ongebruikte medisyne terug aan u apteker.

Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

Inhoud van die pak en ander inligting:

Wat TEVLIGRAF bevat:

Die aktiewe bestanddeel is takrolimus (as monohidraat).

Die ander bestanddele is:

Kapsule-inhoud: etielsellulose, hipromellose (tipe 2910), laktosemonohidraat, magnesiumstearaat.

Kapsuledop: swart ysteroksied (E172), gelatien, ponceau 4R, rooi ysteroksied (E 172), geel ysteroksied (E 172), titaandioksied (E171).

Drukink: swart ysteroksied, kaliumhidroksied, propileenglikol en skellak

Hoe TEVLIGRAF lyk en die inhoud van die pakkie:

TEVLIGRAF 0,5: hardegelatienkapsule van grootte 5 met ’n wit tot afwit poeier. Romp: ligoranje met "0.5 mg" in swart radiaal gedruk. Dop: liggeel met "TR" in swart radiaal gedruk.

TEVLIGRAF 1: hardegelatienkapsule van grootte 4 met ’n wit tot afwit poeier. Romp: ligoranje met "1 mg" in swart radiaal gedruk. Dop: Wit met "TR" in swart radiaal gedruk.

TEVLIGRAF 3: hardegelatienkapsule van grootte 1 met ’n wit tot afwit poeier. Romp: ligoranje met "3 mg" in swart radiaal gedruk. Dop: ligoranje met "TR" in swart radiaal gedruk.

TEVLIGRAF 5: hardegelatienkapsule van grootte 0 met ’n wit tot afwit poeier. Romp: ligoranje met "5 mg" in swart radiaal gedruk. Dop: grysrooi met "TR" in swart radiaal gedruk.

TEVLIGRAF 0,5: Die kapsules is verpak in stulpstroke van PVC/PVDC/aluminium.

Stulpstroke word in multi-laag aluminiumsakkies met droogmiddel verpak.

Pakkies met 30, 50 en 100 verlengde-vrystellende kapsules is beskikbaar.

TEVLIGRAF 1: Die kapsules is verpak in stulpstroke van PVC/PVDC/aluminium. Stulpstroke word in multi-laag aluminiumsakkies met droogmiddel verpak.

Pakkies met 30, 50, 60 en 100 verlengde-vrystellende kapsules is beskikbaar.

TEVLIGRAF 3: Die kapsules is verpak in stulpstroke van PVC/PVDC/aluminium. Stulpstroke word in multi-laag aluminiumsakkies met droogmiddel verpak.

Pakkies met 30, 50 en 100 verlengde-vrystellende kapsules is beskikbaar.

TEVLIGRAF 5: Die kapsules is verpak in stulpstroke van PVC/PVDC/aluminium. Stulpstroke word in multi-laag aluminiumsakkies met droogmiddel verpak.

Pakkies met 30, 50 en 100 verlengde-vrystellende kapsules is beskikbaar.

Nie alle pakgroottes mag noodwendig bemark word nie.

Houer van die registrasiesertifikaat:

Teva Pharmaceuticals (Edms) Bpk

Maxwell Kantoorpark

Magwasingelwes

Waterfall City

Midrand

Gauteng

2090

Tel.: 011 055 0200

Hierdie blad is laas hersien in:

10 November 2022

Registrasienommer:

TEVLIGRAF 0,5: 52/34/0220

TEVLIGRAF 1: 52/34/0221

TEVLIGRAF 3: 52/34/0222

TEVLIGRAF 5: 52/34/0223