PROGRAF[®] 0.5 mg, 1 mg and 5 mg Hard Capsules Tacrolimus monohydrate

Read all of this leaflet carefully before you start using this medicine

Keep this leaflet. You may need to read it again.
 If you have any further questions, ask your doctor or pharmacist.
 This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their 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.

The product is known by the name above but will be referred to as Prograf throughout the rest of this leaflet. In this leaflet:

this leaflet: What Prograf is and what it is used for Before you take Prograf How to take Prograf Possible side effects How to store Prograf Further Information

WHAT PROGRAF IS AND WHAT IT IS USED FOR wref helennes to a group of medicines called immunosuppressants. Following your organ transplant (e.g. liver, kidney, heart), your bo

Frograf belongs to a group of medicines called immunosuppressants. Following your organ transplant (e.g. liver, kidney, heart), your body's immune system will try to reject the new organ. Prograf is used to control your body's immune response enabling your body to accept the transplanted organ. Prograf is othen used in combination with other medicines that also suppress the immune system. You may also begiven Prograf for an ongoing rejection of your transplanted inv, kidney, heart or other organ or if any previous treatment you were taking was unable to control this immune response after your transplantation.

BEFORE YOU TAKE PROGRAF

Do not take Prograf • If you are allergic (hypersensitive) to tacrolimus or any of the other ingredients of Prograf. • If you are allergic (hypersensitive) to any antibiotic belonging to the subgroup of macrolide antibiotics (e.g. erythromycin, clarithromycin

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remeales. 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 Prograf that you receive. If you tell storing 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 Prograf that you receive

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In hy our exposure to sunlight and UV light whild taking Prograf by waring appropriate protective clothing and using a sunscreen with a high say production factor. This is because of the potential risk of malignent sith in changes with immunosuppressive therapy.
Hy our need to have any vaccinations, please inform your docto beforehand. Your doctor will advise you on the best course of action.
Patients therade with Prograf have been reported to have an increased risk of developing lymphoproliferative disorders.
Taking other medicines, herehal or detary supplements
Teli 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.
Prograf tool velos: can be affected by other medicines you take, and blood levels of other medicines can be affected by taking Prograf and not be taken with ciclospoin.
Prograf nust not be taken with ciclospoin.
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Prograf hold relary vorcinazole, effutormovich, clarithrowycin, joasmycin, and ritropicit.
Athrungal medicines and antibiotics (particularly so-called macrolide antibiotics) used to tract infections e.g. ketoconazole, fluconazole, fluconazole, fluconazole, fluconazole, fluconazole, vorcinazole, effutormazole, enthrowycin, loastimycin, and ritropicit.
HUC protease inhibitors (e.g. etherwit, boceprevity, used to tract hepatits).
Antigenesium-aluminium-hydroxide (anticulary so-called macrolide antibiotics) used to tract integration.
Her or bake similar and antibiotis (e.g. entegrating, asquitary), used to tract HIV in

If you are pregrant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your uocur or pharmacies or average before taking this medicine. Prograf is excreted into breast milk. Therefore you should not breast-feed whilst receiving Prograf. Please ask your doctor, healthcare provider or pharmacist for advice before taking any medicine. 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 Prograf. These effects are more frequently observed if Prograf is taken in conjunction with alcohol use. Important information about some of the ingredients of Prograf Prograf contains lackose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

13. HOW TO TAKE PROGRAF.
3. HOW TO TAKE PROGRAF.
Average take Prograf exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Make sure that you neave the same tacrolimus medicine every time you collect your prescription, unless your transplant specialist has agreed to change to a different tacrolimus medicine.
This medicine should be taken wice 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 doces to preven 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 dopends on your general condition and on which other immunosuppressive medication you are taking. Regular blood tests by your doctor will be lique and to ads with dose from time to time. Your doctor will usually reduce your Prograf dose once your condition have the morning and evening. You should generally take Prograf on an empty stomach or at least 1 hour before or 2 to 3 hours after the meal.
The capsules bould be sakenoved whole with a glass of water.

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 tollowing removal from the bottle. Avoid grapefruit and grapefruit juice while taking Prograf. If you take more Prograf than you should If you take more Prograf than you should If you take more Prograf to much Prograf see your doctor or contact your nearest hospital emergency department immediately. If you take more on the take prograf Do not take a double doss to make up for forgotten individual doses. If you have forgotten to take your Prograf capsules, wait until it is time for the you should souble doss to make up for forgotten individual doses. If you have forgotten to take your Prograf capsules, wait until it is time for the you should should hospitate Prograf Double doss to make up for forgotten individual doses. If you have forgotten to take your Prograf capsules, wait until it is time for the you stop taking Prograf

If you stop taking Prograf If you stop taking Prograf Stopping your treatment with Prograf may increase the risk of rejection of your transplanted organ. 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, healthcare provider or pharmacist.

4. POSSIBLE SIDE EFFECTS Like all medicines, Prograf can cause side effects, although not everybody gets them. Prograf 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 Prograf you may therefore catch more infections than usual such as infections of the skin, mouth, stomach and intestines, lungs and urinary tract. Severe side effects may occur, including the ones listed below. Tell your doctor immediately if you have or suspect you may have any of the following serious side effects:

skin, mouth, stomach and intestines, lungs and urinary tract. Severe side effects may occur, including the ones listed below. Tell your doctor immediately if you have or suspect you may have any of the following serious side effects. • Opportunistic antigriture is a finite control of the series of the seri

Increased blood pressure.

• Kidney problems.
Common side effects (may affect up to 1 in 10 people):
• Feduced magnesium, phosphate, potassium, calcium or sodium in the blood, fluid overload, increased uric acid or lipids in the blood, decreased appette, increased acidly of the blood, other changes in the blood saits.
• Andely symptoms, conflusion and disorderstation, depression, mood changes, nightmare, hallucination, mental disorders.
• Fils, disturbances in consciousness, iniping and numbress (sourcembers painful) in the hand sand feet, disziness, impaired writing ability,

Allots grippense
 File, disturbances in consolutionses, lingling and numbress (sometimes painful) in the hands and feet, dizziness, impaired writing ability, nervous system disorders.
 File, disturbances in increased sensitivity to light, eye disorders.
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 File disturbances in threath, changes in the store dissester, educed blood pressure.
 Shorthess in threath, changes in the lung lissue, collection of liquid around the lung, inflammation of the pharynx, cough, flu-like symptoms.
 Shorthess in threath, changes in the lung dissent, constigation, flativity collection of fluid in the belay, vorniting, abdomina pains, indigestion, constigation, flativity, bloirer problems, liver tissue damage and inflammation of the liver.
 Shorthess, reservice 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.
 Insufficient function volue to duride on the discomfort, increase of the enzyme alkaline phosphatase in your blood, weight gain, feeling of temperature disturbed.
 Incommon side effects (may affect up to 1 in 100 people):
 Changes in blood dicting, reduction of lind in and blood cell counts.

Changes in block dotting, reduction in all blood ell cunts. 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.

Blurning of the vision use to autominany in the sector and a sector a sector and a

Dermattis, burning sensation in the sunlight.
 Joint disorders.
 Inability to urinate, painful menstruation and abnormal menstrual bleeding.
 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.
 Rars side effects (may affect up to 1 in 1.000 people):
 Small bleeds in your stin due to blood clots.
 Increased muscle stiffness.
 Bindness.

Increase of fat tissue. 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 pharm

FURTHER INFORMATION
What Prograf or Data
 Prograf 0.5 mg hard capsules
 The active substance is tacrolimus. Each capsule contains 0.5 mg of tacrolimus as tacrolimus monohydrate.
 The other ingredients are:
 • Capsule content: Hydroxypropyl methyl cellulose, lactose, magnesium stearate, croscarmellose sodium.
 Prograf 1 mg hard capsules
 The active substance is tacrolimus. Each capsule contains 1 mg of tacrolimus as tacrolimus monohydrate.
 The other ingredients are:
 • Capsule content: Hydroxypropyl methyl cellulose, lactose, magnesium stearate, croscarmellose sodium.
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The active substance is tacrolimus. Each capsule contains 5 mg of tacrolimus as tacrolimus monohydrate. The other ingredients are:
Capsule content: Hydroxynopy methy cellulose, lactose, magnesium stearate, croscarmellose sodium.
What Prograf Looks like and content of the pack

What Hrograf looks like and content of the pack Prograf 0.5 mg hard capsules Opaque light yellow capsules imprinted in red with '0.5 mg' and "[f] 607", containing white powder. Prograf 1 mg hard capsules Opaque white capsules imprinted in red with "1 mg" and "[f] 617", containing white powder. Prograf 5 mg hard capsules Opaque greyish red capsules imprinted in white with "5 mg" and "[f] 657", containing white powder. Prevares 100 mg of bottle. Pack size of Prograf 0.5 mg, 1 mg and 5 mg: 100 capsules.

5. HOW TO STORE PROGRAF Keep out of the reach and sight of children. Do not store above 30°C. Store in a dry place. Store in the original package in order to protect from moisture. Hard capsules should be taken immediately following removal from the bottle. Do not use Prograf after the expliny date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month. Do not use Prograf after the expliny date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month. Do not use Prograf if you notice visible signs of deterioration. Medicines should not be disposed of via wastewaster or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder. • Saud Arabia Tai: 00966 11 207 8172 Ext: 277.

Council of Arab Health Ministers, Union of Arab Pharmacists THIS IS A MEDICAMENT a product which affects your health, and its co A medicament is a product which affects your health, and its consumption contrary Default to the constraint of the exception of the exception of the exception pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription wholk conclusing your doctor.

Keep medicament out of the reach of children Rev. 12/2017

biolo ciot in a vein or a imm, shock.
 Difficulties in breating, 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

Acute breathlessness.
 Cyst formation in your pancreas.
 Problems with blood flow in the liver.
 Increased hairness.
 Troits, fail, feeling of tightness in your chest, decreased mobilit
 Very rare side effects (may affect up to 1 in 10,000 people):
 Muscular weakness.
 Echocardiogram abnormal.
 Liver failure, narrowing of the bile vessel.
 Painful urination with blood in the urine.
 Increase of tal tissue

Dermatitis, burning sensation in the sunlight.

Deafness. Collection of fluid around the heart Acute breathlessness.

5. HOW TO STORE PROGRAF

FURTHER INFORMATION

Marketing Authorization Holder Hikma Pharmaceuticals

nd Co. I td Killorglin Co. Kern Ireland

Manufacturer Astellas Pharma Tech. Co. Ltd. Toyama Technology Center/ Japan. 2-178 Kojin-machi, Toyama city, Toyama 930-0809

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