

PROGRAF[®] Capsules, PROGRAF[®] XL Capsules, PROGRAF[®] Concentrated Injection

Tacrolimus

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROGRAF or PROGRAF-XL Capsules and PROGRAF Concentrated Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PROGRAF or PROGRAF-XL against the benefits this medicine is expected to have for you.

If you have any concerns about using PROGRAF or PROGRAF-XL ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What PROGRAF / PROGRAF-XL is used for

You have been given a new transplanted liver or kidney, lung or heart from another person because your own was no longer healthy. Your body recognises that this new organ is different from your organs and will try to reject it by attacking it in the same way that it would attack germs that enter your body. This could make you become ill again. PROGRAF or PROGRAF-XL stops this attack; it is very important to take PROGRAF or PROGRAF-XL given to you by your doctor regularly so that your new liver, kidney, lung or heart will not be attacked or rejected.

If you have been taking other medicines for this purpose, but are still feeling unwell, your doctor may change your treatment and begin giving you PROGRAF or PROGRAF-XL.

PROGRAF or PROGRAF-XL contains the active ingredient tacrolimus, which is an immunosuppressive agent.

Your doctor may have prescribed PROGRAF or PROGRAF-XL for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use PROGRAF or PROGRAF-XL

When you must not use it

Do not use PROGRAF or PROGRAF-XL if

- you have an allergy to tacrolimus, other macrolides (these are antibiotics of the erythromycin family – trade names are Eryc, EES, Klacid, Zithromax, Rulide and Biaxsig) or any of the ingredients contained in the capsules. See **Product Description** at the end of this leaflet for a list of ingredients.

Do not use PROGRAF or PROGRAF-XL if the packaging is torn or shows signs of tampering. Do not use PROGRAF or PROGRAF-XL beyond the expiry date (month and year) printed on the pack.

Before you start to use it

You must tell your doctor if

- you are pregnant or planning to become pregnant
- you are using oral contraceptives
- you are breast feeding
- you are receiving cyclosporin immunosuppressive therapy

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given PROGRAF or PROGRAF-XL.

Your doctor will advise you whether or not to take PROGRAF or PROGRAF-XL or if you need to adjust the dose or adapt your treatment.

Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy

without a prescription from a pharmacy, supermarket or health food shop.

This is particularly important for PROGRAF or PROGRAF-XL because there are some specific medicines that could alter PROGRAF's or PROGRAF-XL's effectiveness and safety.

Among these medicines is the herbal preparation St John's Wort (*Hypericum perforatum*) which is capable of decreasing tacrolimus blood levels.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Effects on driving and operating machinery

- PROGRAF or PROGRAF-XL may cause visual or nervous disturbances. If affected, do not drive or operate machinery.

Effects of food and alcohol

- Food reduces the absorption of PROGRAF or PROGRAF-XL so the capsules should be taken at least 1 hour before a meal.

Using PROGRAF or PROGRAF-XL

How much to take:

You can only get PROGRAF or PROGRAF-XL from your doctor. Your dose will be calculated according to your weight, age, and medical condition. As your health and the function of your new liver or kidney, lung or heart can be affected by how much medicine you take, it is normal that your doctor collects samples of blood and urine at regular intervals. This is in order to test whether your medicine requires adjustment.

PROGRAF should be taken in two doses (e.g. morning and evening). PROGRAF-XL should be taken once a day in the morning. Take the capsule from the blister pack and swallow it whole with plenty of water. Do not use grapefruit juice, grapefruit juice contains substances that interfere with the action of PROGRAF or PROGRAF-XL.

How to take it:

- PROGRAF or PROGRAF-XL capsules should be taken at least 1 hour before a meal.
- If you receive PROGRAF Concentrated Injection by intravenous infusion it will be added to a larger volume of diluent and infused over a prolonged period of time (usually 24 hours).
- You must never change the dose yourself even if you are feeling better. It is very important that you keep taking this medicine so that your body will not reject your new liver kidney, lung or heart.

- If you accidentally take a larger dose than recommended, tell your doctor immediately.
- If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to take it

- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

While you are taking PROGRAF or PROGRAF-XL

Things you must do

- Always follow your doctor's instructions carefully
- Tell your doctor if you become pregnant while taking PROGRAF
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking PROGRAF.
- PROGRAF or PROGRAF-XL suppress your immune system by lowering your body's immune defence system. This increases your risk of skin cancer and other cancers while taking PROGRAF or PROGRAF-XL. Always protect yourself from the sun, wear sunscreen, a hat and protective clothing.

Things you must not do

- Do not take PROGRAF or PROGRAF-XL 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.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- tiredness, lack of energy
- stomach upset, including nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach cramps
- tremor (shaking)
- headache
- feeling depressed (sad)
- sleeping difficulties
- blurred vision or sensitive to light
- muscle cramps, tenderness or weakness

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- fever
- diabetes / increased blood sugar
- swelling, numbness or tingling (pins and needles) in your hands and feet
- constant "flu-like" symptoms such as chills, sore throat, aching joints, swollen glands, or any other signs of infection
- unusual bleeding or bruising
- high blood pressure
- palpitations, abnormal heart rhythms, chest pain
- new lumps or moles, or changes to existing moles, anywhere on the body
- swelling of the eyelids, hands or feet due to excess fluid
- a change in the amount of urine passed or in the number of times you urinate, pain on urinating, or other kidney problems.
- yellowing of the skin and/or eyes (jaundice) often accompanied by generally feeling unwell (for

example, tiredness, lack of energy, loss of appetite, nausea and vomiting, pain in the abdomen)

- seizures (fits)
- buzzing or ringing in the ears, difficulty hearing

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using PROGRAF or PROGRAF-XL

Storage

Use all the capsules within 12 months of opening the aluminium wrapper.

Keep PROGRAF or PROGRAF-XL Capsules in the blisters until it is time to take them.

Keep PROGRAF or PROGRAF-XL Capsules in a cool dry place where the temperature is below 25 degrees C. PROGRAF 1 mg and 5 mg Capsules can be stored below 30 degrees C.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store PROGRAF or PROGRAF-XL, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking PROGRAF or PROGRAF-XL Capsules, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product Description

What it looks like

PROGRAF

- PROGRAF 0.5 mg capsules (AUST R 77280) are light yellow, packed in blister sheets of ten capsules and sealed in an aluminium wrapper (Pack size 100 capsules).
- PROGRAF 1 mg capsules (AUST R 58930) are white, packed in blister sheets of ten capsules and

sealed in an aluminium wrapper (Pack size 100 capsules).

- PROGRAF 5 mg capsules (AUST R 58931) are greyish-red (Pack size 50 capsules).

PROGRAF XL

- PROGRAF XL 0.5mg capsules (AUST R 158439) are oblong capsules with a light yellow cap imprinted with “0.5 mg” and an orange body imprinted with “✶647” (Pack size 30 capsules).
- PROGRAF XL 1mg capsules (AUST R 158440) are oblong capsules with a white cap imprinted with “1 mg” and an orange body imprinted with “✶677” (Pack size 60 capsules).
- PROGRAF XL 5mg capsules (AUST R 158444) are oblong capsules with a greyish red cap imprinted with “5 mg” and an orange body imprinted with “✶687” (Pack size 30 capsules).

PROGRAF Concentrated Injection

- PROGRAF Concentrated Injection ampoules (AUST R 58932) contain 5 mg tacrolimus in 1 mL (Pack size 10 ampoules).

Ingredients

PROGRAF Capsules contain hydroxypropylmethyl cellulose, croscarmellose sodium, lactose, and magnesium stearate. The 0.5 mg and 1mg capsules are printed with Opacode S-1-15013, the 5mg capsules with Opacode S-1-17305.

PROGRAF-XL capsules contain hypromellose, ethylcellulose, lactose and magnesium stearate. The capsule shells contain gelatin, titanium dioxide, iron oxide yellow CI77492, iron oxide red CI77491 and sodium lauryl sulfate. The capsules also have a trace of printing ink, Opacode S-1-15083 red, which contains shellac, soya lecithin, simethicone and iron oxide red CI77491.

PROGRAF Concentrated Injection contains polyoxyethylene hydrogenated castor oil and ethanol.

Sponsor

JANSSEN-CILAG Pty Ltd
1-5 Khartoum Road
North Ryde NSW 2113 Australia
Telephone: (02) 8875 3333

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

This leaflet was prepared in March 2010