

TACROLIMUS OINTMENT

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about tacrolimus and tacrolimus Concentrated Injection. It does not contain all the available information. It does not use the place of talking to your doctor or pharmacist.

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

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

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

tacrolimus ointment contains the active ingredient tacrolimus, which is an immunosuppressive agent.

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

Before you use tacrolimus or tacrolimus-

When you must not use it

Do not use tacrolimus or tacrolimus- 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 Biaxig) or any of the ingredients contained in the capsules. See Product Description at the end of this leaflet for a list of ingredients.

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 using or are given tacrolimus or tacrolimus-.

Your doctor will advise you whether or not to use tacrolimus or tacrolimus- or if you need to adjust the dose or adapt your treatment.

using other medicines:

Tell your doctor or pharmacist if you are using any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

This is particularly important for tacrolimus or tacrolimus- because there are some specific medicines that could alter tacrolimus's or tacrolimus-'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 using any of these medicines.

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 using tacrolimus or tacrolimus-

Things you must do

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

Things you must not do

- Do not use tacrolimus or tacrolimus- 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 tacrolimus or tacrolimus-

Storage

Keep tacrolimus in a cool dry place where the temperature is below 25°C. tacrolimus can be stored below 30°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 tacrolimus or tacrolimus-, 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.