Oral tacrolimus products: Updated CHM advice (May 2012)

Questions and answers

What is oral tacrolimus and what is it prescribed for?

Tacrolimus is a medicine that helps control the body’s immune system. “Oral” tacrolimus medicines are prescribed after a liver, heart and kidney transplant operation, to prevent the body from rejecting the new organ. It is also used for the treatment of transplant rejection when other immune treatments have failed.

What are the main risks with this medicine?

If a patient is under dosed there is a risk of loss of the transplanted organ, because of ‘rejection’ by the body’s immune system. On the other hand if the patient is overdosed undesirable effects may be more likely to occur. For this reason, patients need to be carefully monitored so the correct drug level in the blood is maintained. Changes in drug blood levels, even minor, may lead to under dosing or overdosing.

Where can I find out about the potential side effects of my tacrolimus medicine?

Your medicine comes with a Patient Information Leaflet, which describes how to take the medicine and provides advice and information on potential side effects.

What is MHRA recommending?

The MHRA is recommending that to minimise the risk of medication errors caused by inadvertent switching between brands, prescribers should prescribe tacrolimus products by brand name only. Pharmacists should always dispense the exact brand prescribed, and should contact the prescriber if in doubt, to ensure that the correct brand is dispensed.

Why is MHRA making this recommendation now?

There are a growing number of oral tacrolimus medicines available in the UK and the Commission on Human Medicines (CHM) has conducted a review on the safe use of tacrolimus medicines. The conclusion of the review is that there is a potential risk for confusion leading to patients receiving the wrong medicine.
How will the MHRA recommendation affect me?

If you are currently taking an oral tacrolimus medicine you should continue to do so without any changes, as instructed by your doctor. You should take a careful note of the brand name of your usual tacrolimus medicine (see full list below of currently approved products). If you are ever given a tacrolimus medicine with a different brand name you should check straight-away with your pharmacist or doctor that you have been given the correct medicine.

Do I need to be particularly aware regarding my tacrolimus prescription?

Yes, you should be told and should try to remember the exact name of your tacrolimus medicine. The name of the medicine is stated on the label of the medicine and on the patient information leaflet that is supplied with the medicine. If you notice any changes in your prescription or if you are dispensed a different tacrolimus brand or the dosage instructions are different, you should immediately consult your pharmacist or doctor.

How many different brands are there?

There are currently thirteen brands of oral tacrolimus approved in the UK and each one has a unique name, so called brand name.

The three different pharmaceutical forms of oral tacrolimus products are shown below, together with brand names of currently approved products.

- Immediate release capsule taken twice a day (including the following brands - Adoport, Aletris, Capexion, Evenil, Miloprosan, Prograf, Tacni, Takon, Taliximun, Tamitect and Vivadex)
- Prolonged release capsule taken once daily (Advagraf)
- Granules for oral solution taken twice daily (Modigraf).

What if a brand became unavailable?

If a particular brand is not available and a patient has been receiving that particular brand he or she may be switched to an alternative brand. However, this change of brand should only be done under medical supervision and additional tests should be conducted to check the amount of tacrolimus in the blood after the change.

What should a doctor state on a tacrolimus prescription?

A doctor should state the brand name of the particular medicine together with the dose (e.g. 20 mg) and the frequency it should be given (e.g. once a day).
Would the pharmacist have to dispense the same tacrolimus brand stated in the prescription?

Yes, the pharmacist should dispense the particular brand specified in the prescription. If there is any doubt regarding the prescription (for example, the intended brand, or dose), the pharmacist should consult the prescribing physician before dispensing the medicine.

Is it OK if my doctor changes me from one brand of tacrolimus to another?

Yes, you may have a change in the brand of tacrolimus but this should be done only under medical supervision and additional tests should be conducted to check the amount of tacrolimus in the blood after the change.

What should I do if I've forgotten the brand name of my usual medicine?

Your doctor should know the exact brand you are taking so you should check with your doctor first. If are unable to discuss it with your doctor speak to your pharmacist.