

Patient Information
Drugs for Inflammatory Bowel Disease –
Tacrolimus

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If your IBD has not been well controlled, or is flaring up quite often, tacrolimus may be added to your treatment.

What is tacrolimus?

Tacrolimus is an immunosuppressant drug. As well as being used for IBD it is also used to help prevent rejection of organs in patients undergoing organ transplants, such as kidney or liver transplants. It works by reducing the activity of cells in the body's immune system (the system that fights infection), and can reduce inflammation.

Because it reduces the body's defence system it needs to be used with care. Tacrolimus cannot cure your condition. It is normal to expect to be taking tacrolimus for some time although this will depend on your response to the capsules. In some cases you may need to take it in the long term to keep your symptoms controlled.

Tacrolimus works in a similar way to azathioprine/ mercaptopurine (although it is a completely different drug), and is usually given to people who have not got any better on azathioprine/ mercaptopurine, or had side effects meaning they cannot take it.

How do I know it is safe for me to receive tacrolimus?

Before you are able to receive the drug there are a number of questions you will be asked to ensure that tacrolimus is safe for you. This will include questions about your general health, any medication you are taking and vaccines you have received in the past. Checks will be made of your blood pressure, glucose (sugar) levels and kidney tests. You will also have an ECG (recording of your heart rhythm) performed.

You will be advised to have a flu vaccine every year and also a vaccine that helps prevent some types of pneumonia (if you have not received this vaccine previously). In some cases other vaccines may also be advised.

Do I need investigations before commencing tacrolimus?

Yes. You will need to have some up to date blood tests and may also have tests for Hepatitis B and HIV (these are viral infections). If you have not had chicken pox you will also need a blood test to see if you are immune.

You will need to have a chest X- ray within the 3 months before starting tacrolimus. This is to ensure that you do not have tuberculosis (TB), as tacrolimus can, in some cases, re-activate old TB. If necessary a blood test to check for underlying TB will be arranged. It takes a few weeks to get the results of this test before treatment can be started. You will also need to have an ECG (recording of your heart rhythm).

What dose do I take?

This will be decided with your doctor. The dose will be reviewed on a regular basis and changed if needed. In the early stages of treatment, your tacrolimus dose will be gradually increased until you are on the right dose based on your blood tests. Sometimes, it is necessary to change your tacrolimus dose at a later stage. Your IBD Nurse Specialist or Consultant will inform you of any changes that are needed.

Tacrolimus will be prescribed by a brand name (Advagraf, Adoport, Capexion, Modigraf, Prograf, Tacni, Vivadex) and you should always receive the same brand as different preparations may require a different dose.

Tacrolimus will be prescribed by your hospital consultant to start with and may need to be prescribed by the hospital for as long as you are on treatment so please remember to inform your GP that you are taking tacrolimus especially if you need any new medicines or immunisations.

How do I take it?

You should take your tacrolimus capsule(s) twice a day, swallowed whole with a glass of water. It is advisable to take it one hour before food or two to three hours after meals as this improves absorption of the drug into your bloodstream. Within the package there is a drying agent, please ensure that you do not swallow this. If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. **Do not double up on doses.**

It is important not to take your tablets with grapefruit juice as this can affect the ability of the medicine to work.

How long will it take to work?

Tacrolimus does not work immediately, and may take up to 12 weeks to work before it has a full effect. If you respond to tacrolimus you will usually remain on it for many months and perhaps several years, as long as your blood tests are satisfactory.

Can I take other medicines?

Tacrolimus interacts with other medicines including Fluconazole, Erythromycin, Ciclosporin, Omeprazole and St. John's Wort. Always tell your doctor, dentist or pharmacist before taking any other medication. This includes any over the counter medicines, or herbal/ alternative therapies.

Are there any side effects?

Some people report side effects with tacrolimus. These can include:-

- headaches
- nausea & diarrhoea
- muscle cramp
- problems sleeping
- high levels of glucose (sugar) in the blood
- rashes

Please look at the leaflet that came in the medication box for further information on side effects.

If you do pick up a viral infection, such as a cough or cold, it can take longer than usual to get over it.

There have been rare reports of people developing cancer whilst on tacrolimus. These include cancers of the blood such as Lymphoma and Leukaemia and skin cancers. This risk is also recognised with other immunosuppressant drugs such as azathioprine, mercaptopurine or methotrexate as well as the biologics drugs infliximab and adalimumab.

There are some important major side effects of Tacrolimus

- Tacrolimus can on rare occasions affect the bone marrow, resulting in a reduced white blood cell count. This can make you more prone to infection, so it will be necessary to monitor your white blood cell count quite closely while you are taking tacrolimus. We recommend that you have your blood checked at least every three months, and more frequently when you first start the medication.
- **If you come into contact with someone who has chicken pox or shingles, you should see your GP immediately and contact your IBD Nurse Specialist as you may need to attend hospital to have a blood test and start treatment.**
- Hypertension (high blood pressure) can be a side effect of tacrolimus. It is important to have regular checks, so that any problems can be identified. If you do develop hypertension, reducing your dose of tacrolimus is usually effective at treating this.
- Renal (kidney) problems – these are usually reversible, and will be picked up quickly by the blood tests performed to monitor you. Any problems which do develop with the kidneys are usually reversed by reducing or stopping the tacrolimus.
- Reactivation of cold sores or genital herpes may occur. You may require an anti-viral drug such as aciclovir and should see your GP or contact your IBD Nurse Specialist if this happens.

Do I need any special monitoring?

You will need to have your bloods checked on a regular basis. This will be every 2 weeks for the first month of treatment then monthly for 3 months then at least every 3 months for as long as you are taking tacrolimus.

Regular blood tests will help your doctor check how well your body is coping with the tacrolimus, and will decide whether you can continue on treatment. Your Consultant may increase or decrease the dose of tacrolimus you take depending on how well your treatment is controlling your condition, how well you feel and the results of blood tests.

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You will need to have your tacrolimus 'levels' checked, so that any dose changes can be identified. This is a blood test, and is usually done at the same time as your other blood tests. You should attend in the morning for these blood tests and delay the morning dose of tacrolimus until after the blood test.

In addition to blood tests, your blood pressure needs to be checked every two weeks for the first month of treatment, monthly for three months and then no less than every three months thereafter.

Your IBD Nurse Specialist will arrange the blood tests and blood pressure checks with you. These will initially be undertaken in hospital but it may be possible to have these at your GP surgery once you are established on treatment. By doing these regular tests, any potential problems can usually be detected and dealt with promptly.

It is essential to have these blood tests done as directed. It is unsafe to take tacrolimus without having these tests.

Please try to make contact with the IBD Nurse Specialist if you suffer from any of the problems below while you are taking tacrolimus. If for some reason you are unable to get hold of the nurse (or your own doctor) it is suggested that you temporarily stop tacrolimus and report for an urgent blood test if any of the following were to occur:

- Rapidly worsening sore throat
- High temperature that persists for more than 24 hours
- Persistent feeling of sickness or vomiting
- Blackouts

They can arrange for you to have an extra blood test, and advise you about any changes you may need to make to your tacrolimus dose.

What are the benefits of taking tacrolimus?

Tacrolimus may prevent you getting recurrent flares of your condition. It may be a better option for you than other medicines.

Are there alternative treatments available?

There are many alternative immunosuppressant drugs used to treat IBD including azathioprine, mercaptopurine, methotrexate as well as the biologics drugs infliximab and adalimumab. Most patients recommended for tacrolimus have previously tried azathioprine/ mercaptopurine, and either not responded to it or developed unacceptable side effects. In some situations surgery may be necessary. Please discuss all treatment options with your Consultant and IBD Nurse Specialist.

What will happen if I decide not to have treatment with tacrolimus?

You may continue to have ongoing symptoms or your condition may worsen. Please discuss alternative treatments to tacrolimus with your Consultant or IBD Nurse Specialist.

Do I continue my other treatments for IBD?

Yes, unless your hospital doctor or IBD Nurse Specialist advises you to stop any.

What happens if I need an operation?

Let your doctor or nurse know if you need an operation, so that they can advise you on what to do about your tacrolimus. If you are having an operation, in most cases you will be advised to continue with your treatment, but it will help the doctor's plan your care.

What if I need dental treatment?

Please inform your dentist that you are taking tacrolimus. It should not affect routine dental care but it is important to maintain good dental hygiene, brushing and flossing your teeth regularly.

Can I have immunisations whilst on tacrolimus?

Flu vaccinations and Pneumococcal vaccinations are safe to have whilst taking tacrolimus. You should have an annual flu vaccination and the Pneumococcal vaccination which is a once only dose.

You should avoid immunisations with “live” vaccines such as polio, BCG (Tuberculosis), MMR (measles, mumps and rubella) and herpes-zoster (Zostavax). An “inactive” polio vaccine can be given instead of a live one. Close relatives may have “live” vaccines without any risk to you.

Does tacrolimus affect fertility and pregnancy?

As with any medication, special care needs to be taken in women of childbearing age. If you are pregnant, or are planning a pregnancy, it is very important that you inform your doctor, so that you can discuss your treatment with them. Tacrolimus is usually avoided in pregnancy and it is not advisable to take it if you are breastfeeding.

Where can I obtain further information about tacrolimus?

If you have any questions about tacrolimus, ask your Hospital Doctor, GP, IBD Nurse Specialists or your Pharmacist.

Please contact the IBD Nurse Specialists:

Allyson Lewis, Lead Clinical Nurse Specialist (IBD)

Victoria Burn, Clinical Nurse Specialist (IBD)

Karen Evans, Clinical Nurse Specialist (IBD)

On the following number:- 01633 656055 – answer phone or email:- IBDHelp@wales.nhs.uk if you require further information.