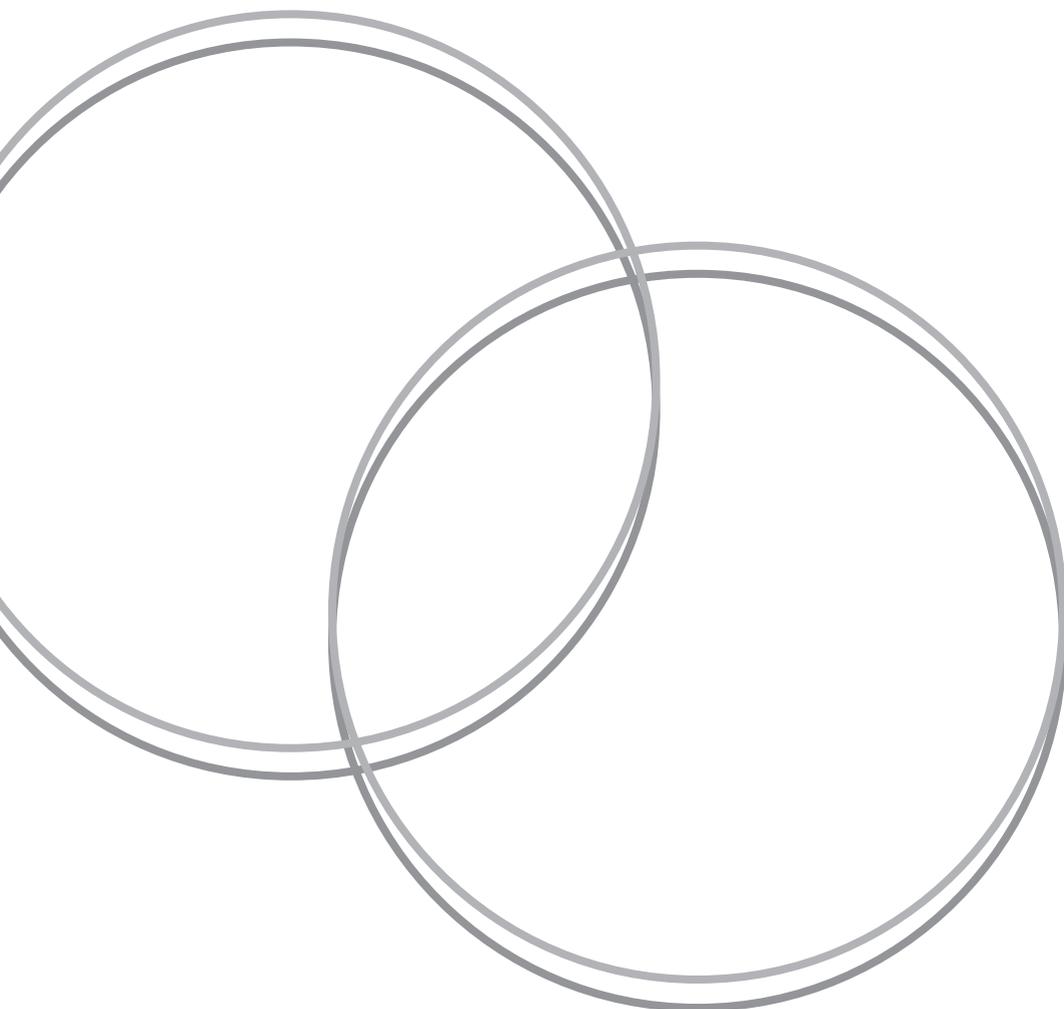




Oxford University Hospitals
NHS Foundation Trust

Tacrolimus suppositories

Information for Patients



This leaflet answers some common questions patients ask.

Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist, IBD nurse specialist or doctor.

Why have I been started on this medicine?

Tacrolimus suppositories are used in patients with proctitis (inflammation of the rectum) who have failed to respond to standard treatments like steroids and aminosalicylates (e.g. mesalazine). This is known as "resistant proctitis".

Tacrolimus suppositories do not have approval to be used for this purpose in the UK a (marketing authorization) for this use currently, so there are no commercial preparation available. However, there are a number of studies where it has been shown that tacrolimus can be effective for proctitis.

How does it work?

Tacrolimus is an immunosuppressant, which means that it reduces the immune response in your body which causes the inflammation that leads to proctitis. Although oral preparations of tacrolimus are available, it is known that rectal preparations such as suppositories are more effective for the treatment of proctitis as they are able to act more locally to the affected area.

What dose do I take?

Each suppository contains 2mg tacrolimus. The dose is one suppository to be inserted into the rectum at night.

How do I take it?

1. Wash your hands thoroughly with soap and water.
2. Remove the suppository from the packaging.
3. Lubricate the tip of the suppository with a water-soluble lubricant (e.g. KY Jelly) which can be bought from any community pharmacy. **Do not use petroleum jelly** (e.g. Vaseline). If a lubricant is not available, moisten the rectal area with water before using.
4. Lie on your side with your lower leg straightened out and your upper leg bent forward towards your stomach.
5. Lift upper buttock to expose the rectal area.
6. Insert the suppository, pointed end first, with your finger until it passes the tightness of the muscular sphincter of the rectum and you feel less pressure (about 2.5cm). If not inserted past the sphincter, the suppository may pop out.
7. Hold the buttocks together for a few seconds. Remain lying down for about 15 minutes after using to avoid the suppository coming out. Try to avoid having a bowel movement for up to an hour after use so that the medication can be absorbed into the body.
8. Wash your hands thoroughly after use.

Rectal preparations must never be taken by mouth.

How long will I be taking it?

The standard course is 2 to 3 months depending on how well you tolerate and respond to the medication. There is little evidence for long term use.

Tacrolimus suppositories are only available via the hospital pharmacy and are made on an individual patient basis. They can therefore take a couple of weeks to arrive after an order is placed.

What happens if I forget to take a dose?

If you remember within 12 hours, take your dose as normal. If more than 12 hours has passed then do not take that day's dose and take your next dose at the normal time. Do not double the dose. If you take too much tacrolimus tell your doctor immediately.

What are the common side effects?

There is limited data on the use of tacrolimus suppositories but the studies available did include reports on the side effects experienced by patients.

Local effects related to use of tacrolimus suppositories may include irritation/burning sensation in the rectum after use.

It is possible that you may absorb enough tacrolimus into the body via the rectum to cause side effects that we know are related to oral tacrolimus. The most common side effects may include:

- An increased susceptibility to infections
- Fever/sore throat
- Increase in blood sugar measurements
- Changes to potassium, magnesium, sodium, calcium and phosphate levels in the blood
- Sleep disturbance, anxiety,
- Headaches
- Tremors
- Increased blood pressure
- Nausea and/or diarrhea
- Changes to your kidney function

Tacrolimus can also increase your susceptibility to sunburn – therefore avoid excessive exposure to sunlight by applying high-factor sun cream and covering the skin when possible. Avoid use of sunbeds whilst on treatment.

If you have any symptoms that develop after you start using the tacrolimus suppositories, please report these to us as soon as possible so we can investigate if they may be related to your treatment.

Do I need any special checks while on tacrolimus suppositories?

The risk of side effects is low. However if high level of tacrolimus are absorbed then you could experience some side effects as listed above. In these cases we would check your blood counts, blood pressure and measure the level of tacrolimus in your blood.

What do I do if I experience side effects?

If you experience any signs of illness or side effects such as unexplained bruising, bleeding, sore throat, fever, cough, shortness of breath, malaise, yellowness of the skin or whites of the eyes, or severe itching (a sign of liver damage), contact your doctor or pharmacist at the hospital . If you are in close contact with anyone who has chicken pox or shingles, inform your doctor as soon as possible.

Does tacrolimus interfere with my other medicines?

Tacrolimus can interact with other medicines, for example carbamazepine, phenytoin, fluconazole, diltiazem, verapamil, clarithromycin, and rifampicin. Always check with the hospital gastroenterology team first before taking any new medication, including any bought over the counter or the internet, and/or any herbal remedies.

Grapefruit juice should be avoided whilst using tacrolimus.

There are reports for those using tacrolimus ointment on the skin that alcohol can increase the risk of facial flushing and skin irritation. These reports do not apply to people taking tacrolimus orally. We cannot say for certain whether this effect will apply to those using the tacrolimus suppositories.

Is tacrolimus OK in pregnancy and breastfeeding?

There is limited data on the use of tacrolimus during pregnancy, but there is no evidence so far that tacrolimus increases the risk of miscarriage, still birth or birth defect,(congenital abnormality).

There is very limited data on the use of tacrolimus whilst breastfeeding. If necessary to continue treatment, the daily dose should be taken immediately after a feed.

If you are planning to become pregnant whilst taking tacrolimus you should first discuss it with your Gastroenterologist.

Keep all medicines out of the reach of children.

Never give any medication prescribed for you to anyone else.

It may harm them even if their symptoms are the same as yours.

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

Authors: Lloyd Thomas & Sarah Cripps, Gastroenterology Pharmacists
May 2021
Review: May 2024
Oxford University Hospitals NHS Foundation Trust
www.ouh.nhs.uk/information



Making a difference across our hospitals

charity@ouh.nhs.uk | 01865 743 444 | hospitalcharity.co.uk

OXFORD HOSPITALS CHARITY (REGISTERED CHARITY NUMBER 1175809)

