

# 0.2% Topical glyceryl trinitrate ointment for chronic anal fissure

Information for the public  
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## About this information

This information explains the evidence summary about the unlicensed use of 0.2% glyceryl trinitrate ointment for treating chronic anal fissure in children, young people and adults. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

## Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality.

Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

## What is chronic anal fissure?

An anal fissure is a common and often painful problem caused by a small tear or ulcer (open sore) in the lining of the anus (back passage). This can cause bleeding, local itching and pain with a bowel movement, which can be severe. When someone has an anal fissure the first treatments can include a high-fibre diet, laxatives and applying anaesthetic ointments to the affected area. Anal fissures usually heal within a few weeks but those that have not healed after 4–6 weeks are called chronic fissures.

If someone has a chronic fissure, it is thought that the reason it has not healed is that the ring muscle (sphincter) that goes around the anus (back passage) has become so tense that the flow of blood to the lining of the anus is reduced. That means that not enough oxygen (carried by the blood) gets to the fissure (or tear). Without enough oxygen, the cells which make up the lining can't grow and repair (heal) the fissure (or tear).

A licensed medicine for treating chronic anal fissure in adults (over 18 years of age) is available in the UK. This is a 0.4% glyceryl trinitrate ointment (also called Rectogesic 4 mg/g Rectal Ointment), and is usually tried for a period of 8 weeks (see [about glyceryl trinitrate](#) for more information). If the person has had to stop treatment with 0.4% glyceryl trinitrate or it hasn't worked, there are other treatments that aren't licensed in the UK which may be tried. These unlicensed treatments include a 0.2% strength of glyceryl trinitrate ointment, diltiazem cream or ointment (see NICE's evidence summary on [2% topical diltiazem hydrochloride for chronic anal fissure](#) for more information), or botulinum toxin injections (such as Botox or other brands) into the area around the anus (back passage). A surgical procedure called sphincterotomy may also be tried.

## About topical glyceryl trinitrate

A topical 0.4% glyceryl trinitrate ointment (also called Rectogesic 4 mg/g Rectal Ointment) is licensed in the UK to treat chronic anal fissure in adults, but not children or young people. Glyceryl trinitrate is commonly abbreviated to GTN and is also sometimes called nitroglycerin. The 0.4% figure gives an indication of the strength of the medicine because it tells us the amount of active ingredient present in the ointment (in this case, the amount of glyceryl trinitrate).

A small amount of the ointment is applied to the affected area twice a day and is used to relieve pain caused by the fissure. The glyceryl trinitrate helps the ring muscle (sphincter) that goes around the anus (back passage) to relax which allows more blood to flow to the lining of the anus (back passage). This may aid the healing process and may relieve the pain.

Treatment with glyceryl trinitrate often causes headache and about 20 in every 100 people using the 0.4% ointment have very bad headaches. These can sometimes be treated successfully with painkillers such as paracetamol but the headache causes some people to stop using the medicine. Some healthcare professionals consider prescribing a 0.2% strength of glyceryl trinitrate ointment (the 0.2% ointment is half as strong as the 0.4% ointment) in the hope it may reduce the number or severity of headaches associated with the 0.4% strength, but still provide pain relief or help heal the fissure. The 0.2% glyceryl trinitrate ointment is not licensed in the UK to treat any medical condition in any age group and is known as an 'unlicensed' medicine.

The 0.2% strength of the ointment is also sometimes used in children and young people because there are no licensed medicines available for treating chronic anal fissure in this age group.

## Summary of possible benefits and harms

A large review of 18 studies, in mostly adults, found that glyceryl trinitrate (used in various strengths) was only slightly better than placebo treatment (one that doesn't contain any active ingredient) at healing chronic anal fissure. This showed that approximately 1 in every 2 people who were using glyceryl trinitrate had a healed fissure compared with approximately 1 in every 3 people who were using placebo (one that doesn't contain any active ingredient). It also found that the anal fissure came back in about half of the people

who seemed to be cured with glyceryl trinitrate.

No studies were found that looked at how well the 0.2% strength of the glyceryl trinitrate ointment worked compared with the 0.4% ointment in treating chronic anal fissure in children, young people or adults.

Just 4 small studies were found that looked at how well different strengths of glyceryl trinitrate ointment (0.1%, 0.2% and 0.4%) worked compared with a placebo ointment (one that doesn't contain any active ingredient). Because these studies didn't compare the different strengths with each other, we don't really know which strengths of ointment are better or worse than the others, including the 0.2% and 0.4% strengths of glyceryl trinitrate.

No studies were found that looked at whether using the 0.2% strength of the glyceryl trinitrate ointment caused fewer headaches than using the 0.4% ointment in children or young people under the age of 18 years.

One small study (181 adults) found that using a lower strength of glyceryl trinitrate caused fewer headaches in adults. The study showed that approximately 1 in every 3 adults who were using the 0.2% glyceryl trinitrate ointment for 8 weeks experienced a headache, compared with approximately 2 out of 3 adults who were using the 0.4% ointment. However, it is important to recognise that these results are from only 47 adults who used the 0.2% ointment and only 37 adults who used the 0.4% strength for 8 weeks. Small studies like this are less reliable than larger ones, and any possible benefits from using a lower strength ointment may have been different if more people had taken part.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with 0.2% glyceryl trinitrate ointment.

## Prescribing 0.2% glyceryl trinitrate ointment

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's [good practice](#)

[guidelines](#). These include giving information about the treatment and discussing the possible benefits and harms so that the patient has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A [full version of the summary aimed at healthcare professionals](#) is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

If your doctor is suggesting that you might try 0.2% glyceryl trinitrate ointment for chronic anal fissure, you might like to ask some of the questions below.

## Questions to ask

- Why am I being offered an unlicensed medicine?
- What does the treatment involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits?
- Could having the treatment make me feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- Will this treatment cure my fissure for good, or can it come back?
- What may happen if I don't have the treatment?

## More information

The evidence summary and this information for the public were produced for NICE by Bazian Ltd.

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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