

Press Release

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First medicine licensed specifically for the relief of chronic anal fissure pain launched in UK

27 May 2005

The only prescription medicine licensed specifically for the relief of chronic anal fissure pain has been launched today in the UK.

Rectogesic is a 0.4% topical nitroglycerin ointment with a novel mode of action in this indication. Nitroglycerin is currently made up to order at 0.2%, but provides inconsistencies with dose due to there being no way of measuring the amount each time it is used. The 'made to order' formulation also has a limited shelf-life.

Rectogesic delivers a standard dose of nitroglycerin based on randomised controlled clinical studies.

- Rectogesic demonstrates a significant reduction ($p < 0.02$) in average pain intensity within the first four days of treatment compared with placebo.¹
- A 50% reduction in pain is seen with Rectogesic in just 18 days.²
- Rectogesic is well tolerated with a stable, predictable and reliable formulation.²
- Rectogesic provides effective pain relief that lasts for up to 12 hours.²

Nitroglycerin ointment works by relaxing the vascular smooth muscle around the anal canal leading to the dilation of peripheral arteries and veins, aiding healing of the fissure.

Rectogesic will be a welcome addition to the treatment options for chronic anal fissures. Surgical repair can be expensive, painful and is associated with both short-term and long-term impairment of continence in up to 30% of patients.³ Additionally, the current use of nitroglycerin has health and safety risks in its production which also makes it very expensive to produce.

Mr Jon Lund, Consultant Surgeon/Senior Lecturer in General Surgery and Coloproctology at Derby City General Hospital commented, "It is good news that healthcare professionals are now able to prescribe a licensed indication of nitroglycerin. Rectogesic is a proven, effective treatment which deals with the cause of anal fissures leading to faster pain relief for patients."

The ointment is applied directly to the affected area and has been shown to significantly and rapidly relieve the pain of chronic anal fissure¹. The ointment is supplied in 30mg tubes with a 2.5cm dosing line on the outside of the carton. A finger covering such as a finger cot or plastic gloves may be placed on the finger to be used to apply the ointment. The finger is placed alongside the guideline on the box and a strip of ointment the length of the line is expressed onto the end of the finger. The amount of ointment expressed is approximately 375mg (1.5mg GTN).

References

1. Bailey HR, Beck DE, Billingham RP, Binderow SR et al. A study to determine the nitroglycerin ointment dose and dosing interval that best promote the healing of chronic anal fissures. *Dis Colon Rectum* 2002; **45**(9): 1192–1199.
2. Data on file, Strakan Ltd.
3. Lund JN, Scholefield JH. A randomized, prospective, double-blind, placebo-controlled trial of glycerol trinitrate ointment in treatment of anal fissures. *Lancet* 1997; **349** (9052): 11-14.

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NOTES TO EDITORS

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Strakan is the UK commercial arm of the ProStrakan Group.

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Photographs available on request:

Rectogesic pack shots