

## **Rectogesic® (Glyceryl Trinitrate) Ointment**

### **Prescribing Information.**

Please refer to the full Summary of Product Characteristics before prescribing

**Presentation:** Rectal Ointment containing Glyceryl Trinitrate (GTN) 4mg/g. **Indications:** Relief of pain associated with chronic anal fissure. **Posology:** A 2.5cm strip of ointment is measured onto the end of a finger, which may be protected by a finger cot, cling film, or other appropriate means. The covered finger is inserted gently into the anal canal up to the first joint and the ointment applied circumferentially. Not for use in children under the age of 18 years. **Contraindications:** Hypersensitivity to glyceryl trinitrate or any of the excipients in the ointment, or to other organic nitrates. Concomitant treatment with phosphodiesterase type 5 inhibitors and with nitric oxide donors such as other long-acting GTN products, isosorbide dinitrate and amyl or butyl nitrite. Postural hypotension, hypotension or uncorrected hypovolaemia; migraine or recurrent headache; increased intracranial pressure; aortic or mitral stenosis; hypertrophic obstructive cardiomyopathy; constrictive pericarditis or pericardial tamponade; marked anaemia or closed-angle glaucoma. **Warnings and Precautions:** Use with caution in patients with severe hepatic or renal disease. Excessive hypotension, especially for long periods of time should be avoided. Paradoxical bradycardia and increased angina pectoris may accompany GTN-induced hypotension. Alcohol may enhance the hypotensive effects of GTN. Patients with acute myocardial infarction or congestive heart failure must be carefully monitored to avoid the potential hazards of hypotension and tachycardia. Treatment should be stopped if haemorrhoid bleeding increases. **Pregnancy and Lactation:** Rectogesic should not be used during pregnancy and is not recommended during breast-feeding. **Driving and Using Machinery:** Patients should be cautioned about driving or using machinery whilst using Rectogesic. **Undesirable Effects:** Very Common; Headache. Common; Dizziness, nausea. Uncommon; Diarrhoea, anal discomfort, vomiting, rectal bleeding, rectal disorder, pruritus, anal burning/itching, tachycardia. Syncope, crescendo angina and rebound hypertension have been reported but are uncommon. Prescribers should consult the summary of product characteristics for further details of side effects. **Pack Size:** 30g tube. **Legal Category:** POM. **Further information is available from the Marketing Authorisation Holders** (see below for details). **Date of prescribing information:** 1<sup>st</sup> December 2023

### **For the United Kingdom:**

**NHS Price:** £39.30 per 30g tube. **Marketing Authorisation Number:** PL 16508/0037. **Marketing Authorisation Holder:** Kyowa Kirin Ltd., Galabank Business Park, Galashiels, TD1 1QH, UK.

**Adverse Events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse Events should also be reported to Kyowa Kirin International UK NewCo Ltd, known as Grünenthal Meds on Tel: +44 (0)1896 664000, email: [PVUK@grunenthalmeds.com](mailto:PVUK@grunenthalmeds.com)**

### **For the Republic of Ireland:**

**Marketing Authorisation Number:** PA 1049/004/001. **Marketing Authorisation Holder:** Kyowa Kirin Holdings B.V. Bloemlaan 22132NP Hoofddorp Netherlands.

**Adverse Events should be reported. Information about adverse event reporting can be found at [www.hpra.ie](http://www.hpra.ie). Adverse Events should also be reported to Kyowa Kirin International NewCo IE Ltd, known as Grünenthal Meds on Tel: +44 (0)1896 664000, email: [PVUK@grunenthalmeds.com](mailto:PVUK@grunenthalmeds.com)**