

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Rectogesic 4 mg/g Rectal Ointment

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glyceryl trinitrate: 4 mg/g.

One gram of rectal ointment contains 40 mg Glyceryl trinitrate in propylene glycol corresponding to 4 mg Glyceryl trinitrate (GTN). The delivered dose from 375 mg of this formulation is approximately 1.5 mg GTN.

The ointment also contains 36 mg Propylene Glycol, and 140 mg Lanolin, per gram rectal ointment.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Rectal ointment.

*Product imported from Greece:*

Off-white smooth opaque ointment formulation.

### 4 CLINICAL PARTICULARS

As per PA1049/004/001.

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1049/004/001.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Propylene glycol  
Lanolin  
Sorbitan sesquioleate  
Hard paraffin  
White soft paraffin

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the tube and outer package of the product on the market in the country of origin.

After first opening: 8 weeks

#### **6.4 Special precautions for storage**

Do not store above 25°C.  
Do not freeze.  
Keep the tube tightly closed.

#### **6.5 Nature and contents of container**

30 g  
Aluminium tubes with white polyethylene non-piercing screw caps

#### **6.6 Special precautions for disposal**

No special requirements

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18,  
Oxleasow Road,  
East Moons Moat,  
Redditch,  
Worcestershire B98 0RE,  
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### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/147/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13<sup>th</sup> February 2015.

### **10 DATE OF REVISION OF THE TEXT**