

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rectogesic 4 mg/g Rectal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect:

Propylene glycol and lanolin

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal ointment.

Product imported from Sweden:

Off-white smooth opaque ointment formulation.

4 CLINICAL PARTICULARS

As per PA2242/018/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/018/001

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 of this product shall be the date shown on the container 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

Pack Size: 30 g

One tube with white non-piercing screw cap.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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Northwest Business Park
Ballycoolin
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/245/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th April 2025

10 DATE OF REVISION OF THE TEXT