

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nitrolingual Pumpspray 400 micrograms per metered dose, sublingual spray.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 400 micrograms glyceryl trinitrate.

Excipients: contains 9.6 mg anhydrous ethanol per metered dose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sublingual spray.

Product imported from the UK:
A clear colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

As per PA0654/020/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0654/020/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut oil
Ethanol Anhydrous
Medium chain partial Triglycerides
Peppermint oil

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.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Red plastic-coated glass bottle (colourless type III glass) fitted with metering pump. Each bottle contains 11.2g solution (equivalent to about 200 doses).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/300/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th January 2013

10 DATE OF REVISION OF THE TEXT

October 2014