

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 the 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 PA2243/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2243/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut oil
Anhydrous ethanol (alcohol)
Medium-chain partial glycerides
Peppermint oil.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 2011

10 DATE OF REVISION OF THE TEXT

May 2018