

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 ethanol.

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

Medium-chain partial glycerides

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 bottle and outer carton 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 fitted with metering pump. Each bottle contains 11.2g of solution (equivalent to about

200 doses).

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/149/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th of May 2011

10 DATE OF REVISION OF THE TEXT

September 2014