

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Elantan LA 50mg Prolonged-Release Capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release hard capsule contains 50 mg isosorbide mononitrate.

Excipients: contains lactose monohydrate and sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard (prolonged-release capsule).

Product imported from the UK:

Size 3 hard gelatin opaque capsule. Brown capsule cap and flesh coloured body, containing white to beige odourless pellets.

4 CLINICAL PARTICULARS

As per PA2118/002/004

5 PHARMACOLOGICAL PROPERTIES

As per PA2118/002/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Hyprolose

Ethylcellulose

Talc

Macrogol 20,000

Sucrose

Corn starch

Gelatin

Titanium dioxide (E171)

Black iron oxide (E172)

Red iron oxide (E172)

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 packaging of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Over-labelled cartons containing 2 blister strips (14 capsules per strip). Pack size of 28 capsules.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/078/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 26th September 2008

10 DATE OF REVISION OF THE TEXT

November 2018.