Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanidip 20mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 20mg lercanidipine hydrochloride which is equivalent to 18.8mg lercanidipine
Excipients with known effect: Lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK
Pink, circular, biconvex tablets, scored on one side and plain on the reverse.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0812/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0812/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Sodium Starch glycolate
Povidone K30
Magnesium stearate
Hypromellose
Talc
Titanium dioxide (E171)
Macrogol 6000
Ferric oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Over-labelled carton containing 2 blister strips (2 x 14 tablets)
Pack size: 28 tablets.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/057/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2009

10 DATE OF REVISION OF THE TEXT

February 2018