Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanidip 20mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20mg lercanidipine hydrochloride which is equivalent to 18.8mg lercanidipine.

Excipients: contains lactose monohydrate 60 mg

For a 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.

4 CLINICAL PARTICULARS

As per PA0812/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0812/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Microcrystalline cellulose
Sodium starch glycollate
Povidone K30
Magnesium stearate

Film coating:
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 container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister pack contained in an over-labelled carton.
Pack size: 28 tablets.

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

LTT Pharma Limited
Unit 18 Oxleasow Road
East Moon Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/021/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th May 2010

10 DATE OF REVISION OF THE TEXT

September 2015