

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanidip 10mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg lercanidipine hydrochloride which is equivalent to 9.4mg lercanidipine.

Excipient(s) with known effect: Contains lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

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

4 CLINICAL PARTICULARS

As per PA0812/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0812/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose monohydrate
Microcrystalline cellulose
Sodium starch glycolate
Povidone K30
Magnesium stearate

Film coat:

Hypromellose
Talc
Titanium dioxide (E171)
Macrogol 6000
Iron 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

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

Blister packs containing 28 (UK, reboxed and over-labelled & Italian reboxed) or 50 tablets (German, reboxed) contained in an outer cardboard carton.

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/193/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 February 2007

Date of last renewal: 23 February 2012

10 DATE OF REVISION OF THE TEXT

April 2016