Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ZANIDIP 20 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Czech Republic:
Pink, circular, biconvex tablets of 8.5 mm, scored on one side. The tablet can be divided 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

Tablet core:
Lactose monohydrate
Microcrystalline cellulose
Sodium carboxymethyl starch (type A)
Povidone 40
Magnesium stearate

Film coating mixture:
Hypromellose
Talc
Titanium dioxide (E171) Macrogol 6000
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 blister 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.

6.5 Nature and contents of container

Aluminium/ PVC blisters.
Packs of 28 tablets.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/203/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd February 2024

10 DATE OF REVISION OF THE TEXT