# 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 of lercanidipine hydrochloride equivalent to 9.4mg 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*
Yellow, 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 PA0812/001/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0812/001/001

## 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 shall be 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.
The package should be kept in a dry place.
Do not store above 25°C.

**6.5 Nature and contents of container**

Cardboard outer containing aluminium/opaque PVC blister. Pack size 28.

**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**

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
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Ballycoolin
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**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/134/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 29th February 2008

**10 DATE OF REVISION OF THE TEXT**

April 2020