

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanidip 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg lercanidipine hydrochloride equivalent to 9.4 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 the Czech Republic

Yellow, circular, biconvex tablet of 6.5 mm, scored on one side.

The score line 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 (Type A)

Povidone 40

Magnesium stearate

Film coating mixture:

Hypromellose

Talc

Titanium dioxide (E171)

Macrogol 6000

Yellow 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/opaque PVC blister.
Packs of 28 film-coated 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/481/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2021

10 DATE OF REVISION OF THE TEXT

July 2023