

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:

One film-coated tablet contains 60 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Germany

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

poly(O-carboxymethyl) starch sodium salt

Povidone K30

Magnesium stearate

Film coating mixture:

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 packaging 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 blisters.
Packs of 28 tablets.

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4/C3
Metropoint Business Park
Kettles Lane
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K67 RH92
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/034/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th April 2025

10 DATE OF REVISION OF THE TEXT