

# 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:

One film-coated tablet contains 30 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Germany*

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

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 blister.

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  
Swords  
Co Dublin  
K67 RH92  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23080/034/001

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

Date of first authorisation: 4<sup>th</sup> April 2025

## **10 DATE OF REVISION OF THE TEXT**