

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Istin 10 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

Product sourced from the Netherlands, Hungary and Romania: white, octagonal tablets with 'AML-10' on one side and 'Pfizer' on the other.

Product sourced from Italy: white, octagonal tablets with 'AML' and '10' on either side of a scoreline on one side and 'Pfizer' on the other.

## 4 CLINICAL PARTICULARS

As per PA23055/012/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23055/012/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium hydrogen phosphate anhydrous,  
Magnesium stearate  
Microcrystalline cellulose  
Sodium starch glycolate

### 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

Do not store above 25° C.  
Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Blister packs containing 28 or 30 tablets, contained in an outer cardboard carton.  
Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

Any unused 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**

PPA0465/065/002

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

Date of first authorisation: 17 November 2000  
Last updated: October 2021

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

April 2023