

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Istin 5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product sourced from Hungary and the Netherlands: white, octagonal tablets with 'AML-5' on one side and 'Pfizer' on the other.

Product sourced from Italy, Romania and Czech Republic: white, octagonal tablets with 'AML' and '5' on either side of a scoreline on one side and 'Pfizer' on the other. The 5 mg tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA23055/012/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/012/001

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 is the date shown on the blister and outer carton of the product as marketed 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

PPA0465/065/001

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

May 2024