

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Istin 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amlodipine Besilate equivalent to 5 mg Amlodipine.

Excipients:

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK:

White to off white, emerald shaped tablets engraved AML-5 and breaker score on one side and "Pfizer" as logo on the other side. The 5mg tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0019/045/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/045/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate anhydrous
Magnesium stearate
Microcrystalline cellulose
Sodium starch glycolate Type A

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Do not store above 25°C.

6.5 Nature and contents of container

Opaque PVC/PVDC blister calendar packs with aluminium foil backing containing 28 tablets.

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

Lexon (UK) Ltd
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2011

10 DATE OF REVISION OF THE TEXT

November 2018