

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Istin 10mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amlodipine Besilate equivalent to 10mg 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-10 on one side and Pfizer logo on the other side.

4 CLINICAL PARTICULARS

As per PA0019/045/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/045/002

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 in an overlabelled carton 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

PPA1097/061/002

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