

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 of Amlodipine
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK

10mg: White to off white, emerald shaped tablet engraved 'AML-10' on one side and 'Pfizer' as 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

Microcrystalline cellulose E460
Dibasic calcium phosphate anhydrous
Sodium starch glycollate
Magnesium stearate E572

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container 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

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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/010/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2009

10 DATE OF REVISION OF THE TEXT

August 2015