

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ikorel 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Nicorandil 10 mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from: UK

Round, off-white, circular tablets with faceted edges, scored on one side and with the marking 'IK10' on the other side. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0540/102/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/102/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch
Croscarmellose sodium
Stearic acid
Mannitol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin. Each blister strip should be used within 30 days of opening.

6.4 Special precautions for storage

Do not store above 25°C. Keep the blister strip in the outer carton in order to protect from moisture.

6.5 Nature and contents of container

Blister strips of 10 tablets including 1 drying agent in a cardboard outer. Pack size: 60

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

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/160/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2011

10 DATE OF REVISION OF THE TEXT

November 2014