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 the UK
Round, off-white, circular tablets with faceted edges, scored on one side and with the marking ‘IK10’ on the other side. Tablets 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

Maize starch
Croscarmellose sodium
Stearic acid
Mannitol

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 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. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister strips of 10 tablets per silica gel dessicant. Each tablet is connected via a channel to the dessicant capsule. Pack sizes: cartons of 60 tablets in blister strips.

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

PPA1463/088/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation**:** 25th of November 2013

10 DATE OF REVISION OF THE TEXT

October 2014