Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ikorel 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg nicorandil.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the Netherlands and the United Kingdom
Round, white tablets with 'IK10' on one side and a breakline 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 (E421)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

After opening
Each blister strip should be used within 30 days of opening at below mentioned storage conditions.

6.4 Special precautions for storage

Do not store above 25 °C.
Store in the original packaging in order to protect from moisture.

6.5 Nature and contents of container

Ikorel Tablets are presented in soft tempered aluminium foil/PVC blister strips of 10 tablets, in which each tablet is linked to a silica gel capsule dessicant.

Blister pack containing 30 or 60 tablets, in outer cardboard carton.
Not all pack sizes may be marketed.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/103/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 November 2003

10 DATE OF REVISION OF THE TEXT

September 2018