

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ikorel 10 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Nicorandil 10mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.  
Product imported from the Netherlands and the UK  
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.  
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**

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.

Product imported from the Netherlands and the UK

Blister pack containing 30 or 60 tablets, in an overlabelled outer cardboard carton.

Not all pack sizes may be marketed

Product imported from the UK

Blister pack containing 60 tablets in an outer cardboard carton.

## **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**

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 2015