

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cordarone X 200 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amiodarone hydrochloride 200 mg.

Excipient: Each tablet contains Lactose Monohydrate

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the Netherlands, Czech Republic, and Hungary:*

Round, white tablet with a breakline, '200' and a logo on one side, plain on the other side.

*Product imported from the UK:*

Round, white tablet with a breakline on one side, '200' and a logo on the other side.

The breakline is only to facilitate breaking for ease of swallowing and not to be divided into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0540/142/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/142/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate

Maize starch

Povidone

Colloidal anhydrous silica

Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

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

#### **6.4 Special precautions for storage**

Do not store above 25°C.

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

#### **6.5 Nature and contents of container**

Blisterpacks of 30 in a carton and 28 or 60 tablets in an overlabelled outer 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**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/119/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 05 March 2004

Date of last renewal: 05 March 2009

### **10 DATE OF REVISION OF THE TEXT**

November 2019