

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cordarone X 100 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg amiodarone hydrochloride.

Excipient(s) with known effect

Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the United Kingdom*

Round, white tablet with a break line on one side imprinted 100 on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0540/142/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/142/001

## 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 for this product shall be the date shown on the blister 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.

Keep the blister in the outer carton in order to protect from light.

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

Blister packs of 28 tablets in cardboard cartons.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon (UK) Ltd  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1097/051/001

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

Date of first authorisation: 3<sup>rd</sup> August 2018

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