

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cordarone X 100 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amiodarone Hydrochloride 100mg.

Excipients: lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

Round, white tablet with a breakline on one side, '100' and a logo on the other side.

The scoreline 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 of this product shall be the date shown on the container and outer package 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

Cordarone X 100mg tablets are supplied in PVC/aluminium blister packs of 28 tablets in an overlabelled 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 Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/119/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 2014

10 DATE OF REVISION OF THE TEXT

November 2019