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.

Excipients: Each tablet contains lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Greece.

Round, white with a break line on one side imprinted 200 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 PA0540/142/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/142/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Polyvinyl K-90
Colloidal silicon dioxide
Magnesium stearate
Lactose monohydrate
Purified water

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 strip in the outer carton in order to protect from light.

6.5 Nature and contents of container

Cordarone X 200 mg tablets are supplied in PVC/aluminium blister packs of 30 tablets further packed in cardboard cartons.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/020/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th July 2020

10 DATE OF REVISION OF THE TEXT

February 2022