

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cordarone X 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amiodarone Hydrochloride 200 mg.
Excipients: Each tablet contains 96mg lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from UK:

Round, white with a breakline on one side imprinted 200 on the other.

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

4 CLINICAL PARTICULARS

As per PA0540/142/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/142/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Maize starch
Colloidal anhydrous Silica
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton 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

Cordarone X 200mg tablets are supplied in blister packs of 28 tablets further packed in cardboard cartons.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/094/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th January 2014

10 DATE OF REVISION OF THE TEXT

November 2015