

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 with known effect: Each tablet contains lactose (as 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 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 silicon dioxide

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 strip 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 30 tablets further packed in cardboard cartons.

6.6 Special precautions for disposal and other handling

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

PPA1463/255/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th December 2025

10 DATE OF REVISION OF THE TEXT