

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cordarone X 100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains amiodarone hydrochloride 100mg.
Excipient: lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the United Kingdom

Product imported as Amiodarone Hydrochloride: Round, white tablets with a breakline on one side and imprinted ‘S75’ and ‘STERWIN’ on the other.

Product imported as Cordarone X: Round, white tablets with a breakline on one side and marked ‘100’ and a logo on the other side.

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 container 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.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

Re-boxed cardboard outer containing blister strips. Pack size 28.
Overlabelled outer carton containing blister strips. Pack size 28

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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/084/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd October 2008

10 DATE OF REVISION OF THE TEXT

October 2015