

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 with known effect: lactose monohydrate.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the United Kingdom:

Round, white with a breakline on one side imprinted 100 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 PA0540/142/001

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 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. Store in the original package 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 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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/112/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd May 2014

10 DATE OF REVISION OF THE TEXT

January 2015