

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardura XL 8mg Prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Doxazosin mesilate: 9.70 mg equivalent to 8 mg doxazosin.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Spain:

Cardura XL 8mg Prolonged- release tablets are white round, biconvex shaped tablets with an orifice on one side, marked ‘CXL8’.

4 CLINICAL PARTICULARS

As per PA 0822/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Polyethylene oxide
- Sodium chloride
- Hydroxypropylmethylcellulose
- Red ferric oxide (E172)
- Magnesium stearate
- Cellulose acetate
- Polyethylene glycol (Macrogol) 3350
- Titanium dioxide (E171)
- Shellac
- Black iron oxide (E172)
- Isopropyl alcohol
- Ammonium hydroxide
- Propylene glycol

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 Store below 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Calendar packs of 28 tablets.

Aluminium foil/aluminium foil blister strips in a carton.

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

PPA1562/003/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th March 2014

10 DATE OF REVISION OF THE TEXT

January 2017