Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardura XL 4mg Prolonged – release tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4mg doxazosin (as mesilate).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from the Netherlands, Poland, UK and Spain:
White, round, biconvex shaped tablets marked ‘CXL 4’ or white, round, biconvex shaped tablets within an orifice on one side, marked 'CXL 4'.

4 CLINICAL PARTICULARS

As per PA0822/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/004/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

List of excipients for products imported from the Netherlands and the UK
Propylene Glycol
Polyethylene oxide
Sodium chloride
Hypromellose
Red ferric oxide (E172)
Titanium dioxide (E171)
Magnesium stearate
Cellacefate
Macrogol
Pharmaceutical glaze
Black iron oxide (E172)
Ammonium Hydroxide (E527)

List of excipients for products imported from Spain
Polyethylene oxide
Sodium chloride
Hypromellose
Red ferric oxide (E172)
Titanium dioxide (E171)
Magnesium stearate
Cellulose acetate

Macrogol 3350
Pharmaceutical glaze
Black iron oxide (E172)
Ammonium hydroxide
Propylene glycol
Shellac
N-butyl alcohol
Isopropyl alcohol

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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30^{o}C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs containing 28 or 30 tablets.

Not all pack sizes may be marketed.

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/095/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2003
Date of first renewal: 17th October 2010

10 DATE OF REVISION OF THE TEXT

July 2015