Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardura XL 4mg Prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 4mg doxazosin (as mesilate)
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablets.
Product imported from the UK and Romania
Cardura XL 4mg are white, round, biconvex-shaped tablets with an orifice on one side, marked 'CXL4' and plain on the other.

4 CLINICAL PARTICULARS

As per PA0822/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/004/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Imported from UK
Polyethylene oxide
Sodium chloride
Hypromellose
Red ferric oxide (E172)
Titanium dioxide (E171)
Magnesium stearate
Cellulose acetate
Macrogol
Pharmaceutical glaze
Black iron oxide (E172)
Ammonium hydroxide
Propylene glycol

Imported from Romania
Polyethylene oxide
Sodium chloride
Hypromellose
Red ferric oxide (E172)
Titanium dioxide (E171)
Magnesium stearate
Cellulose acetate
Macrogol 3350
Opadry white Y5-2-7063 (contains hypromellose, macrogol 3350, titanium dioxide (E171))

Black ink (Opacode S-1-8106, contains pharmaceutical glaze, black iron oxide (E172), n-butanol, methanol, ammonium hydroxide)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of 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 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminium foil blister strips in a cardboard carton. Blister packs of 28 tablets.

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
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 11th May 2007

Date of last renewal: 11th May 2012

10 DATE OF REVISION OF THE TEXT

September 2015