

## 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 the full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Prolonged-release tablets

*Product imported from the UK:*

Cardura XL 4mg prolonged-release tablets are white round, biconvex shaped tablets with an orifice on one side, marked 'CXL4'.

### 4 CLINICAL PARTICULARS

As per PA0822/004/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/004/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

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

#### 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 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 and other handling**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/003/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of First Authorisation: 28th May 2009

Date of Last Renewal: 28th May 2014

### **10 DATE OF REVISION OF THE TEXT**

January 2017