

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cardura XL 8 mg 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 France*

White, film coated, round, biconvex shaped tablets with an orifice on one side, marked CXL8.

## 4 CLINICAL PARTICULARS

As per PA23355/001/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/001/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride  
Hypromellose  
Red ferric oxide (E172)  
Titanium dioxide (E171)  
Magnesium stearate  
Cellulose acetate  
Macrogol  
Pharmaceutical glaze  
Black iron oxide (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

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

**6.5 Nature and contents of container**

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**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/479/001

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

Date of first authorisation: 24<sup>th</sup> August 2021

**10 DATE OF REVISION OF THE TEXT**

September 2022