

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 PA0822/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/004/002

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: 24th August 2021

10 DATE OF REVISION OF THE TEXT