

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

Polyethylene oxide

Sodium chloride

Hypromellose

Red ferric oxide (E172) Titanium dioxide (E171) Magnesium stearate Cellulose acetate Macrogol Pharmaceutical glaze

Propylene glycol

Black iron oxide (E172) 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

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/140/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th September 2020

10 DATE OF REVISION OF THE TEXT