Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vesomni 6 mg/0.4 mg modified release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains a layer of 6 mg solifenacin succinate, corresponding to 4.5 mg solifenacin free base and a layer of 0.4 mg tamsulosin hydrochloride, corresponding to 0.37 mg of tamsulosin free base.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release tablet

Product imported from Greece and Czech Republic
Red, round film-coated tablet debossed with "6/0.4".

4 CLINICAL PARTICULARS

As per PA1241/016/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/016/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421) Maltose
Macrogol
Magnesium stearate (E470b) Butylhydroxytoluene (E321)
Colloidal silica anhydrous (E551)
Hypromellose (E464)
Iron oxide red (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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs containing 30x1 tablets packaged in an outer carton.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/452/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th January 2020

10 DATE OF REVISION OF THE TEXT

May 2021