

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 Bulgaria

Each tablet is round, approximately 9 mm in diameter, red film-coated and 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 7,000,000
Macrogol 8000
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

The medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium blister packs containing 30 tablets.

6.6 Special precautions for disposal and other handling

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

PPA1463/139/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th September 2020

10 DATE OF REVISION OF THE TEXT