# 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 Czech Republic.*

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,
Magnesium stearate (E470b)
Butylhydroxytoluene (E321),
Colloidal anhydrous silica (E551),
Hypromellose (E464),
Red iron oxide (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited
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Harcourt Centre
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**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/012/001

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

Date of first authorisation: 14th July 2017

**10 DATE OF REVISION OF THE TEXT**

February 2022