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 Spain
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 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 is the date shown on the container and outer carton of the product as marketed 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

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
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Metropoint Business Park,
Kettles Lane,
Swords,
Co Dublin,
K67 RH92
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th March 2024

10 DATE OF REVISION OF THE TEXT