Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omnexel 400 micrograms, prolonged release tablets, film-coated.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged release film-coated tablet contains 400 micrograms tamsulosin hydrochloride.
Excipients:
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated, prolonged release tablets.
(Oral Controlled Absorption System, OCAS).
Product sourced from France:
Approximately 9 mm in diameter, round, bi-convex, yellow, film-coated and debossed with the code '04'.

4 CLINICAL PARTICULARS

As per PA 1241/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1241/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Macrogol 7,000,000
Macrogol 8,000
Magnesium stearate (E470b)
Butylhydroxytoluene (E321)
Colloidal anhydrous silica (E551)

Tablet coat:
Macrogol 8,000
Hypromellose (E464)
Iron oxide yellow (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 container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in the original package.
This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

Aluminium/aluminium foil blister packs containing 30 tablets in an over labelled outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/096/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th April 2009

10 DATE OF REVISION OF THE TEXT

November 2014