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 0.4 mg tamsulosin hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated, prolonged release tablet

Product imported from the Netherlands, Hungary, France, Spain, Greece and Poland
Approximately 9 mm in diameter, round, bi-convex, yellow, film-coated and debossed with the code '04'.

4 CLINICAL PARTICULARS

As per PA1241/006/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/006/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from France, Spain, Greece, Poland and the Netherlands:
Macrogol 7,000,000
Macrogol 8,000
Magnesium stearate (E470b)
Butylhydroxytoluene (E321)
Colloidal anhydrous silica (E551)
Hypromellose (E464)
Iron oxide yellow (E172)

Product imported from the UK:
Macrogol
Butylhydroxytoluene
Hypromellose
Magnesium stearate
Yellow iron oxide

Product imported from Hungary:
Magnesium stearate
Macrogol 7,000,000
Macrogol 8,000

Film-coating:
Opadry yellow O3F22733 (Hypromellose, macrogol 8000, Iron oxide yellow (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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C

6.5 Nature and contents of container

Blister pack containing 30 tablets contained in an overlabelled outer cardboard carton.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/171/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First authorisation: 18 November 2005

Date of last Renewal: 18 November 2010

10 DATE OF REVISION OF THE TEXT

September 2022