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 0.4mg tamsulosin hydrochloride.

Excipients:
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated, prolonged release tablet.
(Oral Controlled Absorption System, OCAS)

Product imported from Poland:
Approximately 9mm 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

Macrogol
Magnesium stearate (E470b)
Butylhydroxytoluene (E321)
Colloidal silica anhydrous (E551)
Hypromellose (E464)
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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium foil blister strips in an overlabelled cardboard carton 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 2009

10 DATE OF REVISION OF THE TEXT

March 2023