

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Omnixel, 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 the UK and 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**

January 2016