

# 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 400 micrograms 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, the UK 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 silica anhydrous (E551)  
Hypromellose (E464)  
Iron oxide yellow (E172)

Product imported from the UK:  
Macrogol  
Buthylhydroxytoluene  
Hypromellose  
Magnesium sterate  
Yellow iron oxide

Product imported from Hungary:  
Magnesium stearate  
Macrogol 7,000,000  
Macrogol 8,000  
Film-coating:  
Opadry yellow 03F22733 (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  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 0465/171/001

## **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**

February 2017