Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hytrin 5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg terazosin (as terazosin hydrochloride dihydrate).

Excipient(s) with known effect
Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK
A tan round flat, bevel edged tablet embossed with the ‘Abbott’ logo and triangular facets on one face and plain on the other.

4 CLINICAL PARTICULARS

As per PA1142/005/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1142/005/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Purified talc
Magnesium stearate
Dye (iron oxide burnt sienna, 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 the 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 of 28 tablets contained in an 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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/161/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation: 30 September 2005

Date of last Renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

August 2018