Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xatral 10mg Prolonged Release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg alfuzosin hydrochloride.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet, prolonged release

Product imported from Greece, the UK and Italy:
Round three layer tablet with one white layer between two yellow layers.

4 CLINICAL PARTICULARS

As per PA0540/162/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/162/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Hydrogenated castor oil
Ethylcellulose
Yellow ferric oxide (E172)
Magnesium stearate
Colloidal hydrated silica
Mannitol (E421)
Povidone
Microcrystalline cellulose

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.
Keep in the original package.

6.5 Nature and contents of container

Blister pack of 30 tablets contained in an over-labelled 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

PPA0465/138/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 February 2005
Date of last renewal: 11 February 2010

10 DATE OF REVISION OF THE TEXT

November 2014