

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 6.1.

3 PHARMACEUTICAL FORM

Tablet, prolonged release

Product imported from Italy and the UK:

Round biconvex three layer tablet; one white layer between two yellow layers.

4 CLINICAL PARTICULARS

As per PA0540/162/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/152/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylcellulose 20
Hydrogenated castor oil
Hypromellose
Yellow ferric oxide
Magnesium stearate
Microcrystalline cellulose,
Povidone
Silica colloidal hydrated
Mannitol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be 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. Store in the original package.

6.5 Nature and contents of container

30 tablets in PVC/foil blister strips in an over-labelled outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/104/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th May 2009

10 DATE OF REVISION OF THE TEXT

February 2015