Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xatral 2.5mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg alfuzosin hydrochloride.
Excipients: Also contains Lactose monohydrate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-Coated Tablet.

Product imported from UK

White round, film coated tablet engraved on one side with ‘Xatral 2.5’.

4 CLINICAL PARTICULARS

As per PA0540/162/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/162/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Microcrystalline cellulose
Lactose
Povidone
Sodium starch glycollate
Magnesium stearate.

Coating
Methylhydroxypropylcellulose
Polyethylene glycol 400
Titanium dioxide suspension (E171).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC.
Store in the original package.

6.5 Nature and contents of container

Boxes with 60 tablets in PVC/foil blister strips.

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

LTT Pharma Limited
Unit 18, Oxleasow Road,
East Moons Moat,
Redditch,
Worcestershire B98 0RE
United Kindgom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/020/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th June 2014

10 DATE OF REVISION OF THE TEXT

December 2014