

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 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 PA0540/162/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

ethylcellulose
hydrogenated castor oil
hypromellose
iron oxide yellow (E172)
magnesium stearate
microcrystalline cellulose
povidone
colloidal hydrated silica
mannitol

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 strips and outer carton 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

Boxes with tablets in PVC/foil blister strips, 30 tablets per pack.

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 Moon Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th March 2010

10 DATE OF REVISION OF THE TEXT

December 2014