

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xatral 10mg Prolonged Release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg alfuzosin hydrochloride.

Excipient(s) with known effect

Hydrogenated castor oil

For the 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
Yellow ferric oxide (E172)
Magnesium stearate
Microcrystalline cellulose
Povidone
Silica colloidal hydrated
Mannitol (E421)

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

Blister strips in a cardboard carton.
Pack size 30 tablets.

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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation :18th January 2008

10 DATE OF REVISION OF THE TEXT

April 2018