

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet, prolonged release.

Product imported from the UK and Italy:

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
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 is the date shown on the container 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 of 30 tablets in blister strips. Each pack contains 3 blister strips of 10 tablets in an over-labelled cardboard outer 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th March 2009

10 DATE OF REVISION OF THE TEXT

March 2018