

# 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