

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Casodex 50mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg of bicalutamide.

Excipient(s) with known effect:  
lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet.

*Product imported from Italy:*  
Round, white, biconvex tablet intagliated with “CDX50” on one face, and a logo on the reverse.

## 4 CLINICAL PARTICULARS

As per PA0970/004/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0970/004/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose Monohydrate  
Sodium Starch Glycolate (Type A)  
Povidone  
Magnesium Stearate  
Hypromellose  
Macrogol 300  
Titanium Dioxide

### 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 packaging of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 30°C. Store in the original package.

## **6.5 Nature and contents of container**

Calendar packs of 14 tablets in an over-labelled outer carton.  
Pack size: 28 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**

Clear Pharmacy  
157-173 Roden Street  
Belfast BT12 5QA  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1596/049/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1st April 2011

## **10 DATE OF REVISION OF THE TEXT**

November 2016