

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Casodex 50 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg bicalutamide.  
Excipient: contains lactose monohydrate.  
For a 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 Glycollate (Type A)  
Povidone  
Magnesium Stearate  
Hypromellose  
Macrogol 300  
Titanium Dioxide (E171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

Do not store above 30°C.

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

Cardboard outer containing blister strips.  
Pack size: 28

## **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**

PPA1151/104/001

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

Date of first authorisation: 24th April 2009

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

January 2015