

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Casodex 50 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg of bicalutamide.

Excipient(s) with known effect:

Each tablet contains lactose monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Romania.*

Round, white, biconvex tablet intagliated with CDX50 on one face and a logo on the reverse.

## 4 CLINICAL PARTICULARS

As per PA1019/008/001.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/008/001.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Core

Lactose monohydrate

Magnesium stearate

Povidone (K 29-K 32)

Sodium starch glycolate

#### Film-coating

Hypromellose

Macrogol 300

Titanium dioxide (E171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package 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**

PVC blister/aluminium foil packs of 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

#### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited  
Block 3  
Harcourt Centre  
Harcourt Road  
Dublin 2  
Ireland

#### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/037/001

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

Date of first authorisation: 6<sup>th</sup> November 2020

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

October 2021