

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 50mg 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 tablets 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 (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 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

6.5 Nature and contents of container

Blister packs of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/068/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th March 2018

10 DATE OF REVISION OF THE TEXT