

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 bicalutamide.

Excipient with known effect:

Lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece, Italy and Romania:

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

4 CLINICAL PARTICULARS

As per PA23154/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23154/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Sodium starch glycollate

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 container 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

Blisters of 28 film-coated 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

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/144/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisations: 02 July 2004

Date of last renewal: 02 July 2009

10 DATE OF REVISION OF THE TEXT

March 2022