

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 Greece and Romania:

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

4 CLINICAL PARTICULARS

As per PA 23154/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 23154/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Lactose Monohydrate

Sodium Starch Glycolate Povidone

Magnesium Stearate

Film coating

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 the 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

PVC blister/aluminium foil packs. 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/107/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th April 2016

10 DATE OF REVISION OF THE TEXT

December 2021