Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bicalutamide 50 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg of Bicalutamide.

Excipients with known effect:

Each tablet contains Lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet. (tablets)

Product imported from The Netherlands

White to off white, round biconvex, film-coated tablet debossed 'B 50' on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per PA 2315/079/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 2315/079/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Sodium starch glycollate (Type A)
Povidone K-30
Magnesium stearate

Film-coating:
Hypromellose E5
Titanium dioxide E171
Macrogol 400

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

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Tablets are packed in PVC-PVdC/aluminium blisters
Bicalutamide 50 mg Film-coated Tablets are packed in blisters of 30 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

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

PPA23176/038/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th November 2020

10 DATE OF REVISION OF THE TEXT

October 2021