

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arimidex 1 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 1 mg anastrozole.

Excipients with known effect

Also contains lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy, Poland, Spain, The Czech Republic and Greece:

White, round, biconvex tablet marked 'A' on one side and 'Adx1' on the other side.

4 CLINICAL PARTICULARS

As per PA 23154/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 23154/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Povidone

Sodium starch glycolate

Magnesium stearate

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 original package.

6.5 Nature and contents of container

PVC blister/aluminium foil pack of 28 tablets contained in a carton.

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/218/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th May 2009

10 DATE OF REVISION OF THE TEXT

June 2022