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 of anastrozole.

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 the Czech Republic
White, round, biconvex film-coated tablet approximately 6.1 mm in size marked 'A' on one side and 'Adx1' on the other side.

4 CLINICAL PARTICULARS

As per PA23154/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23154/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K29-32)
Sodium starch glycolate
Magnesium stearate
Hypromellose
Macrogol 300
Titanium dioxide

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.

6.5 Nature and contents of container

Blisters of 28 film-coated tablets.

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 MARKETING AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PPA2306/017/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2019

10 DATE OF REVISION OF THE TEXT

October 2021