

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.

Excipient(s) with known effect:

Also contains lactose(see section 4.4).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product Imported from Latvia and Poland

White, round, biconvex tablet with logo on one side and 'adxl' on the other side.

4 CLINICAL PARTICULARS

As per PA0970/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Povidone

Sodium starch glycollate

Magnesium stearate

Hypromellose

Macrogol

Titanium dioxide

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 packaging.

6.5 Nature and contents of container

Blister packs of 28 tablets in an over-labelled cardboard carton.

6.6 Special precautions for disposal and other handling

Any unused 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

PPA1463/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th September 2012

10 DATE OF REVISION OF THE TEXT

February 2019