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:
Each film-coated tablet contains lactose monohydrate (see section 4.4).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product Imported from Czech Republic and Poland
White, round, biconvex tablet with '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
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 carton of the product as marketed 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

April 2024