

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arimidex 1mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 1 mg anastrozole.

Excipients with known effect: Each film-coated tablet contains 93mg of 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 Poland and Italy:

White, round, biconvex tablet, with a logo on one side and strength on the other.

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 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. Store in the original package.

6.5 Nature and contents of container

Blister packs in a cardboard carton of 28 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

Clear Pharmacy
157-173 Roden Street
Belfast
BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th July 2011

10 DATE OF REVISION OF THE TEXT

October 2014