

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: each film-coated tablet contains 93.0mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film Coated Tablet (Tablet)

Product imported from Spain and Italy:

White, biconvex, 6 mm in diameter embossed with a logo on one side and a tablet strength marking on the other.

4 CLINICAL PARTICULARS

As per PA 970/3/1

5 PHARMACOLOGICAL PROPERTIES

As per PA 970/3/1

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Sodium starch glycolate
Magnesium stearate
Hypromellose
Macrogol
Titanium Dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Over-labelled outer carton containing blister strips.
Pack size: 28

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/161/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st October 2011

10 DATE OF REVISION OF THE TEXT

October 2014