

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anastrozole 1 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1 mg of anastrozole.

Excipient(s) with known effect

Each 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 the UK:

White to off-white, film-coated round-shaped tablet, debossed with numbers "93" on one side and "A10" on the other side.

4 CLINICAL PARTICULARS

As per PA0749/028/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/028/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Lactose monohydrate

Magnesium stearate (E572)

Povidone K-30

Sodium starch glycolate type A

Coating

Hypromellose (E464)

Macrogol 400 and macrogol 6000

Titanium dioxide (E171)

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blisters of 28 film-coated tablets in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st May 2015

10 DATE OF REVISION OF THE TEXT

September 2016