Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aromasin 25 mg coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: exemestane
Each coated tablet contains 25 mg exemestane.
Each tablet contains sucrose and methyl parahydroxybenzoate (E218).
For a full list of Excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet.

Product imported from Greece.
Round, biconvex, off-white coated tablet marked 7663 on one side.

4 CLINICAL PARTICULARS

As per PA0822/111/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/111/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Silica, colloidal hydrated
Crospovidone
Hypromellose
Magnesium stearate
Mannitol
Microcrystalline cellulose
Sodium starch glycolate (type A)
Polysorbate

Sugar-coating:
Hypromellose
Polyvinyl alcohol
Simeticone
Macrogol
Sucrose
Magnesium carbonate, light
Titanium dioxide (E171)
Methyl Parahydroxybenzoate (E218)
Cetyl esters wax
Talc
Carnauba wax

Printing ink:
Ethyl alcohol
Shellac
Iron oxides (E172)
Titanium oxide (E171)

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

Store in the original package.

6.5 Nature and contents of container

30 tablets in blister packs (Aluminium-PVDC/PVC-PVDC)

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/155/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th of April 2015

10 DATE OF REVISION OF THE TEXT