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 25mg exemestane.
Each tablet contains 30.2mg of sucrose and 0.003mg of methyl parahydroxybenzoate (E218).
For a full list of Excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated tablet.
Product imported from UK (as Aromasin & Exemestane)
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

Product imported from UK as Exemestane

Silica, colloidal hydrated
Crospovidone
Hypromellose
Magnesium stearate
Mannitol
Microcrystalline cellulose
Sodium starch glycolate (type A)
Polysorbate
Polyvinyl alcohol
Simeticone
Macrogol
Sucrose
Magnesium carbonate, light
Titanium dioxide (E171)
Methyl Parahydroxybenzoate (E218)
Cetyl esters wax
Talc
Carnauba wax
Shellac
Iron oxides (E172)
Titanium oxide (E171)

Product imported from UK as Aromasin

silica colloidal hydrated

crospovidone
hypromellose
magnesium stearate
mannitol
microcrystalline cellulose
sodium starch glycollate (type A)
polysorbate
polyvinyl alcohol
simeticone
macrogol
sucrose
magnesium carbonate light
methyl parahydroxybenzoate (E218)
cetyl esters wax
talc
carnauba wax
shellac
ethyl alcohol
titanium oxide (E171)
iron oxides (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed 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

Blister packs of 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/178/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th May 2012

10 DATE OF REVISION OF THE TEXT

February 2020