

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aromasin 25 mg coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each coated tablet contains 25 mg exemestane.

Excipients with known effect: Each tablet contains sucrose and Methyl Parahydroxybenzoate (E218).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet

Product imported from Italy, Lithuania and Bulgaria:

Round, biconvex, off-white coated tablets 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 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

Do not store above 30°C.
Store in the original package.

6.5 Nature and contents of container

Blister strips of 15 tablets in an outer carton.
Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/236/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2009

10 DATE OF REVISION OF THE TEXT

June 2022