

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 of exemestane.

Excipients with known effect

Sucrose

Methyl parahydroxybenzoate (E218)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet

Product imported from Lithuania

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

Silica, colloidal hydrated (E551)

Crospovidone

Hypromellose (E464)

Magnesium stearate (E572)

Mannitol (E421)

Microcrystalline cellulose (E460)

Sodium starch glycolate (type A)

Polysorbate 80 (E433)

Polyvinyl alcohol

Simeticone

Macrogol 6000

Sucrose

Magnesium carbonate, light (E504)

Methyl Parahydroxybenzoate (E218)

Cetyl esters wax

Talc

Carnauba wax

Ethyl alcohol

Shellac

Titanium Dioxide (E171)

Black Iron Oxide (E172)

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 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

Blisters of 30 coated tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2019

10 DATE OF REVISION OF THE TEXT