

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 and Bulgaria:

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
Crospovidone
Magnesium stearate
Mannitol
Microcrystalline cellulose
Sodium starch glycolate (type A)
Polysorbate
Hypromellose
Polyvinyl alcohol
Simeticone
Macrogol
Sucrose
Magnesium carbonate, light
Titanium dioxide (E171)
Methyl Parahydroxybenzoate (E218)
Cetyl esters wax
Talc
Carnauba wax
Ethyl alcohol
Shellac
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 container and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Product imported from Italy:

This medicinal product does not require any special temperature storage conditions.
Store in the original package.

Product imported from Bulgaria:

Do not store above 30°C.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/069/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st August 2012

10 DATE OF REVISION OF THE TEXT

June 2023