

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Exemestane 25 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 25 mg exemestane
Excipients with known effect:
Each film-coated tablet contains mannitol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablets.

Product imported from the United Kingdom.

White to off white, round, biconvex film-coated Tablet with ‘E25’ on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1390/026/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1390/026/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Mannitol
Cellulose Microcrystalline
Crospovidone
Sodium Starch Glycolate (Type A)
Hypromellose E5
Polysorbate 80
Colloidal anhydrous silica
Magnesium Stearate

Tablet coating

Hypromellose 6cp (E464)
Titanium dioxide (E171)
Macrogol 400

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

This product does not require any special storage conditions.

6.5 Nature and contents of container

Packs contain 30 Film-coated Tablets in White opaque blister packs of 30 tablets.

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

Any unused product or waste should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/184/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2016

10 DATE OF REVISION OF THE TEXT