

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Megace 160 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Megestrol Acetate 160 mg.
Excipient with known effect:
Each tablet contains Lactose Monohydrate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White, oval, biconvex tablets with a breakline scored on one side and engraved ‘160’ on the other side.
Product imported from Greece
The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1696/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1696/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose,
lactose monohydrate,
magnesium stearate,
povidone,
colloidal anhydrous silica,
sodium starch glycolate.
Purified water.

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

Do not store above 25°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/194/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2017

10 DATE OF REVISION OF THE TEXT