Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Megace 160mg 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

Product sourced from Greece:
Off-white, oval, biconvex tablets with a breakline, engraved ‘160’ on one face.
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

Colloidal anhydrous silica
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Povidone
Sodium starch glycollate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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 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

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/323/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2017

10 DATE OF REVISION OF THE TEXT