Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Megace 40 mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of suspension contains 40 mg micronized megestrol acetate.

Excipients with known effect:
Sucrose
Sodium benzoate
Sodium
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

Product imported from Poland:
White to cream coloured milky suspension

4 CLINICAL PARTICULARS

As per PA1696/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1696/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Lemon-lime flavour
Polyethylene glycol
Polysorbate 80 (E433)
Sodium benzoate (E211)
Sodium citrate (E331)
Sucrose
Water
Xanthan gum (E415)

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

6.5 Nature and contents of container

240 ml bottle contained in an overlabelled cardboard carton.

Also contains a 30ml measuring cup.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/323/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th November 2013

10 DATE OF REVISION OF THE TEXT

November 2019