Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Megace 40 mg/ml oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of oral suspension contains 40 mg of megestrol acetate.

Excipients with known effect
Sucrose
Sodium benzoate (E211)

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 1450
Polysorbate 80
Sodium benzoate (E211)
Sodium citrate dihydrate
Sucrose
Purified water
Xanthan gum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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

High density polyethylene bottle with a child-resistant closure containing 240 ml oral suspension.

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

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2019

10 DATE OF REVISION OF THE TEXT