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 (E211)
Sodium
Ethanol, a component of the lemon-lime flavour

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 PA22698/024/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22698/024/001

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

High density polyethylene bottles with a child-resistant closure available in 240 ml.
Also contains a 30 ml 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/161/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2021

10 DATE OF REVISION OF THE TEXT

July 2023