# 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

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**