

# 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

Ethanol (0.49 mg/ml), 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, Portugal and Lithuania:*

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

*Products imported from Poland and Portugal:*

Citric acid anhydrous

Lemon-lime flavour

Polyethylene glycol

Polysorbate 80 (E433)

Sodium benzoate (E211)

Sodium citrate (E331)

Sucrose

Water

Xanthan gum (E415)

*Products imported from Lithuania:*

Citric acid anhydrous

Lemon-lime flavour

Macrogol 1450

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 is the date shown on the container and outer carton of the product as marketed in the country of origin.

Shelf life after first opening the bottle - 14 days - Store in a refrigerator (2 °C - 8 °C).

Shelf life after first opening the bottle - 7 days - Store below 30 °C.

## **6.4 Special precautions for storage**

Do not store above 25 °C.

For storage conditions after first opening of the medicinal product, see section 6.3.

## **6.5 Nature and contents of container**

Plastic bottle with plastic closure.

Each pack contains one bottle containing 240 ml oral suspension and a measuring cup.

## **6.6 Special precautions for disposal**

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: 4<sup>th</sup> November 2013

## **10 DATE OF REVISION OF THE TEXT**

June 2026