

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Megace 40 mg/ml Oral Suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Megestrol acetate 40 mg/ml.

Also contains Sucrose.

For a 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  
Sodium benzoate  
Sodium citrate  
Sucrose  
Water  
Xanthan gum

#### 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  
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**

January 2017