

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

One-Alpha 1 microgram soft capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 1 microgram of alfacalcidol.

Excipient(s) with known effects: Sesame oil

For the full list of excipients see section 6.1

## 3 PHARMACEUTICAL FORM

Capsule, soft (capsule)

*Product imported from Greece:*

Brown, egg-shaped soft-gelatin capsule holding 0.1g oily solution

## 4 CLINICAL PARTICULARS

Asper PA 2239/017/001

## 5 PHARMACOLOGICAL PROPERTIES

Asper PA 2239/017/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sesame oil  
All-rac- $\alpha$ -tocopherol

*Capsule shell*

Gelatin  
Glycerol (E422)  
Potassium sorbate (E202)  
Red iron oxide (E172)  
Black iron oxide (E172)

### 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 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**

Blister pack of 30 capsules contained in an over labeled outer cardboard carton.

#### **6.6 Special precautions for disposal and other handling**

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/134/002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 10 September 2004

Date of last renewal: 10 September 2009

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

July 2022