

# 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 effect: 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

As per PA2239/017/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2239/017/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sesame Oil, refined  
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

Al/PVC blister foil, polyamide/Al lid containing 30 capsules.

## **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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/167/001

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

Date of first authorisation: 28<sup>th</sup> May 2021

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

April 2022