Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

One-Alpha 0.25 micrograms soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.25micrograms of alfacalcidol
Excipient-Sesame oil
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft (capsule)
Product imported from the UK:
Cream-coloured, egg shaped soft gelatin capsule holding 0.1g oily solution

4 CLINICAL PARTICULARS

As per PA0046/024/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/024/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sesame Oil
All-rac-α-tocopherol
Gelatin
Glycerol (E422)
Potassium Sorbate (E202)
Titanium Dioxide (E171)

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

Overlabelled outer container containing blister strips
Pack size: 30 capsules

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/116/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 10th July 2009

10 DATE OF REVISION OF THE TEXT

November 2016