

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: contains 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 PA 0046/024/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0046/024/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sesame oil
All-rac- α -tocopherol
Gelatin
Glycerol
Potassium sorbate
Ferric oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/139/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th December 2014

10 DATE OF REVISION OF THE TEXT