

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

IDEOS 500mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Calcium carbonate 1250mg (equivalent to 500mg calcium) and Cholecalciferol (Vitamin D₃) 400 I.U. (equivalent to 10µg).

Excipients with known effects: 475mg sorbitol, 1.52mg sucrose, 0.3mg hydrogenated soya bean oil.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets

Product imported from Greece:

Greyish white, square, tablets

4 CLINICAL PARTICULARS

As per PA1033/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1033/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)

Sorbitol (E420)

Povidone

Lemon flavouring*

Magnesium stearate

* Composition of the lemon flavouring: Flavouring preparations, natural flavouring substances, maltodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole.

Excipients in Vitamin D3 concentrate: alpha-tocopherol, partially hydrogenated soyabean oil, gelatin, sucrose, maize starch.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the tube container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in the original container.
Do not store above 25°C.

6.5 Nature and contents of container

Tubes containing 15 tablets with stopper containing desiccant. Pack sizes: 60 tablets (4 tubes in an over labelled cardboard carton).

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/202/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th April 2013

10 DATE OF REVISION OF THE TEXT

March 2015