

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ideos 500 mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients per tablet:
Calcium carbonate 1250 mg
(equivalent to 500 mg of elemental calcium)
Cholecalciferol (vitamin D3) 400 IU
(equivalent to 10 µg)

Excipients with known effects: sorbitol, sucrose, hydrogenated soybean oil.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets.

Product imported from Spain & Greece:
Greyish white square chewable tablets, with a lemon flavour.

4 CLINICAL PARTICULARS

As per PA1033/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1033/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Spain:
Xylitol (E967)
Sorbitol (E420)
Povidone
Lemon flavouring*
Magnesium stearate

*Composition of the lemon flavouring: essential oils of lemon, orange, litsea cubeba, maltodextrin, acacia gum, sodium citrate.
The vitamin D3 concentrate may contain sucrose and soyabean oil.

Product imported from Greece:
Xylitol (E967)
Sorbitol (E420)
Povidone
Lemon flavouring *
Magnesium stearate

*Composition of the lemon flavouring (flavouring preparations, natural flavouring substances, maldodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole)

Excipients in Vitamin D3 concentrate (cholecalciferol): 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 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. Store in the original container.

6.5 Nature and contents of container

4 x Polypropylene tubes containing 15 tablets each (60 tablets in total) contained in an outer cardboard carton.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/128/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 June 2004

Date of last renewal: 11 June 2009

10 DATE OF REVISION OF THE TEXT

January 2015