

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

IDEOS 500mg/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 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 PA0133/001/001

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 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

Outer carton containing 4 tubes with a stopper. Each tube contains 15 tablets.
Pack sizes: 60 tablets.

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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/202/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2013

10 DATE OF REVISION OF THE TEXT

January 2015