

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

IDEOS 500mg/400 IU Chewable Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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 France:*  
Greyish white, square, tablet.

## 4 CLINICAL PARTICULARS

As per PA 1033/001/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1033/001/001

## 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**

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 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**

Primecrown 2010 Limited  
4/5 Northolt Trading Estate  
Belvue Road  
Northolt  
Middlesex UB5 5QS  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1633/033/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 11th October 2013

## **10 DATE OF REVISION OF THE TEXT**

September 2016