

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Kalcipos-D forte 500 mg/800 IU chewable tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains calcium carbonate equivalent to 500mg calcium and cholecalciferol 20 microgram corresponding to 800 IU Vitamin D3.

Excipients of known effect: glucose 200mg and sucrose 1.8mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable Tablet

*Product imported from the UK*

White to off-white, round, chewable tablet engraved R152 on one side, diameter 17 mm.

## 4 CLINICAL PARTICULARS

As per PA1051/008/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1051/008/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Liquid spray dried glucose

Magnesium stearate

Sodium citrate

Xylitol

All-*rac*-alfa-tocopherol

Acacia

Sodium laurilsulphate

Sucrose

Medium chain triglycerides

Starch sodium octenyl succinate (E1450)

Silicon dioxide  
sodium ascorbate

## **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 as marketed in the country of origin.

Shelf-life after first opening container: 6 months

## **6.4 Special precautions for storage**

Store in the original container, in order to protect from light.  
Keep container tightly closed in order to protect from moisture.

## **6.5 Nature and contents of container**

Plastic container with screw cap  
Pack size: 30

## **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 Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/162/001

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

Date of first authorisation: 16<sup>th</sup> January 2015

**10 DATE OF REVISION OF THE TEXT**

January 2019