

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Calcichew-D3 Forte Chewable Tablets, calcium carbonate/colecalciferol equivalent to 500mg calcium/400IU colecalciferol

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per tablet:

Calcium carbonate (equivalent to 500mg of elemental calcium)	1250mg
Colecalciferol (equivalent to 10micrograms vitamin D3)	400 IU

Also Contains sorbitol, isomalt, aspartame and sucrose.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable tablet.

*Product imported from the UK:*

Round, white, uncoated and convex tablet. May have small specks.

## 4 CLINICAL PARTICULARS

As per PA1547/007/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1547/007/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sorbitol (E420)  
 Povidone  
 Isomalt (E953)  
 Fatty acid mono- and diglycerides  
 Magnesium stearate  
 Lemon flavor  
 Aspartame (E951)  
 Sucrose  
 Tocopherol  
 Modified maize starch  
 Medium chain triglycerides  
 Sodium ascorbate  
 Anhydrous colloidal silica

## **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 30°C. Keep the container tightly closed to protect from moisture.

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

White, high density polyethylene bottles.

Bottles containing 60 and 100 tablets with tamper evident seal. Bottles containing 60 tablets are available in overlabelled cardboard cartons and bottles containing 100 tablets are available in reboxed cardboard cartons.

## **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**

B & S Healthcare  
Unit 4, Bradfield Road  
Ruislip  
Middlesex  
HA4 0NU  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/209/001

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

Date of first authorisation: 24<sup>th</sup> November 2014

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