

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcichew-D₃ Forte 500 mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per tablet:

Calcium carbonate 1250 mg
(equivalent to 500 mg of elemental calcium)

Colecalciferol 400 IU
(equivalent to 10 micrograms vitamin D₃)

Excipients with known effect: Sucrose, sorbitol (E 420), isomalt (E953), aspartame (E951).

For the 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 PA2229/005/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2229/005/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Povidone
Isomalt (E953)
Flavouring (lemon)
Fatty acid mono- and di-glycerides
Aspartame (E951)
Magnesium stearate
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 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 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 or 100 tablets with tamper evident seal. Not all pack sizes may be marketed.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/156/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th September 2007

10 DATE OF REVISION OF THE TEXT

November 2020