

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).

Excipient(s) with known effect: isomalt (E953) and sucrose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

Product imported from Spain:

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

4 CLINICAL PARTICULARS

As per PA2239/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/013/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)
Povidone
Isomalt (E953)
Flavouring (lemon)
Fatty acid mono- and diglycerides
Sucralose (E955)
Magnesium stearate
Sucrose
Modified maize starch
Triglycerides, medium-chain
Sodium ascorbate
Silica, colloidal anhydrous
Tocopherol

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 of 60 chewable tablets contained in an outer cardboard carton.

6.6 Special precautions for disposal

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

PPA0465/156/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th October 2022

10 DATE OF REVISION OF THE TEXT