Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcichew-D_3 Forte 500 mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per tablet:

Calcium carbonate (equivalent to 500 mg of elemental calcium)	1250 mg
Colecalciferol (equivalent to 10 micrograms vitamin D_3)	400 IU

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 the United Kingdom
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

Xylitol (E967)
Povidone
Isomalt (E953)
Fatty acid mono- and di-glycerides
Magnesium stearate
Lemon flavour
Sucralose (E955)
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 for 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, plastic bottles.

Bottles containing 60 tablets with tamper evident seal.

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

LTT Pharma Limited
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Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/100/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2013

10 DATE OF REVISION OF THE TEXT

April 2018