

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcichew 500mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains calcium carbonate 1250 mg equivalent to 500mg of elemental calcium.

Excipient(s) with known effect:

Isomalt (E953)

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 PA2229/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2229/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)

Povidone

Magnesium stearate

Sucralose (E955)

Isomalt (E953)

Flavouring (orange)

Mono, di-fatty acid glycerides

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

Container with screw cap containing 100 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon(UK)Ltd
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th December 2018

10 DATE OF REVISION OF THE TEXT