

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcichew 500 mg chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect

Isomalt (E953)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

Product imported from Greece

White, round chewable tablets with orange flavour.

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

Flavouring (orange)

Magnesium stearate

Sucralose (E955)

Isomalt (E953)

Monoglycerides and diglycerides of fatty acids

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 bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Bottles of 60 chewable tablets contained in an outer cardboard carton.

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/156/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 December 2005

Date of last renewal: 02 December 2010

10 DATE OF REVISION OF THE TEXT

November 2018