

# 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 Spain:*

White, round chewable tablets with orange flavour.

## 4 CLINICAL PARTICULARS

As per PA2239/013/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2239/013/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Xylitol (E967) Povidone

Isomalt (E953)

Magnesium stearate

Sucralose (E955)

Flavour enhancer (orange)

Monoglycerides and diglycerides of fatty acid

### 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

Plastic Bottle 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**

IMED Healthcare Ltd,  
Unit 625 Kilshane Avenue,  
Northwest Business Park,  
Ballycoolin,  
Dublin 15,  
Ireland.

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/218/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> June 2024

**10 DATE OF REVISION OF THE TEXT**