Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Calcium Carbonate 500mg Chewable Tablets

calcium carbonate

PL 43461/0128

Flamingo Pharma UK Ltd.

LAY SUMMARY

Calcium Carbonate 500mg Chewable Tablets
calcium carbonate

This is a summary of the Public Assessment Report (PAR) for Calcium Carbonate 500 mg Chewable Tablets. It explains how this product was assessed and its authorisation recommended, as well as its/their conditions of use. It is not intended to provide practical advice on how to use this product/these products.

This product will be referred to as Calcium Carbonate Tablets in this lay summary for ease of reading.

For practical information about using Calcium Carbonate Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Calcium Carbonate Tablets and what is it used for?
This application is for a medicine that has a well-established use. This means that the use of the active substance in this medicine has been well-established in the UK/European Union for at least 10 years, with recognised efficacy and an acceptable level of safety.

Calcium Carbonate Tablets are orange flavour fast-acting tablets which get to work within minutes to provide effective relief from heartburn, indigestion and acid reflux.

How does Calcium Carbonate Tablets work?
Calcium Carbonate Tablets contain the active ingredient, calcium carbonate which belongs to a group of medicines called antacid. Each antacid tablet works powerfully to neutralise excess acid in the stomach.

How is Calcium Carbonate Tablets used?
The pharmaceutical form of this medicine is a chewable tablet, and the route of administration is oral (by mouth).

Adults and children over 12 years only:
2 tablets to be sucked or chewed, as required, preferably 1 hour after meals and before bedtime. For heartburn an extra 2 tablets may be taken between these times. The patient should *not* take more than 16 tablets a day.

Children under 12 years:
This medicine is *not* recommended for children under 12 years.

If symptoms persist after 14 days, the patient should consult their pharmacist or doctor. Prolonged use should be avoided.

For further information on how Calcium Carbonate Tablets is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can be obtained without a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Calcium Carbonate Tablets have been shown in studies?
As the active substance Calcium Carbonate Tablets has been in clinical use for over 10 years, data were provided in the form of literature references to show that Calcium Carbonate Tablets is a safe and effective relief from heartburn, indigestion and acid reflux.

What are the possible side effects of Calcium Carbonate Tablets?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on behalf of someone else they care for, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Why was Calcium Carbonate Tablets approved?
It was concluded that the data provided from literature references had shown that Calcium Carbonate Tablets is effective in the relief from heartburn, indigestion and acid reflux. Furthermore, the well-established use of the active substance Calcium Carbonate Tablets has shown that it has a recognised efficacy and an acceptable level of safety. Therefore, the MHRA decided that the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Calcium Carbonate Tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Calcium Carbonate Tablets. The RMP details the important risks of Calcium Carbonate Tablets, how these risks can be minimised, any uncertainties about Calcium Carbonate Tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Calcium Carbonate Tablets.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Calcium Carbonate Tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Calcium Carbonate Tablets
A Marketing Authorisation for Calcium Carbonate Tablets was granted in the United Kingdom (UK) on 30 July 2025.

The full PAR for Calcium Carbonate Tablets follows this summary.

This summary was last updated in December 2025.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Calcium Carbonate 500 mg Chewable Tablets (PL 43461/0128) could be approved.

The product is approved for the following indication:
For the symptomatic relief of indigestion, heartburn, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, overindulgence in food and drink, indigestion during pregnancy, acid indigestion, and nervous indigestion.

Calcium Carbonate 500 mg Chewable Tablets contain the active ingredient, calcium carbonate.

Calcium carbonate reacts with excess acid in the gastric juice to produce soluble chloride.

$$CaCO_3 + 2HCl \rightarrow CaCl_2 + H_2O + CO_2$$

Calcium carbonate has a rapid and powerful neutralising action.

In healthy volunteers, a significant increase in the pH of stomach contents above baseline pH was achieved between 1 and 6 minutes after dosing.

This application was approved under Regulation 54 of The Human Medicines Regulation 2012, as amended (previously Article 10a of Directive 2001/83/EC, as amended), as a well-established use application. No new non-clinical or clinical studies were submitted, as the data submitted for these applications is in the form of literature references.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation for Calcium Carbonate 500 mg Chewable Tablets was granted in the United Kingdom (UK) on 30 July 2025.

II QUALITY ASPECTS

II.1 Introduction

The active ingredient is calcium carbonate.
Each 500 mg chewable tablet contains 500 mg of calcium carbonate.

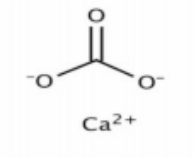
In addition to calcium carbonate, this product also contains the following excipients: potato starch, sucrose, pregelatinised starch, sodium saccharin, Trusil orange ASV 030002 flavour (IFF), citric acid anhydrous, magnesium stearate and altered tangerine yellow.

The finished product is packaged in aluminium foil- PVC film blisters or aluminium foil-PVC/PVDC film blister packs and are available in pack-sizes of 8, 12, 24, 32, 36, 48, 60, 64, 72, 84, 96 or 120 tablets.
Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

II.2 ACTIVE SUBSTANCE

rINN: Calcium carbonate
Chemical Name: Calcium carbonate
Molecular Formula: $CaCO_3$
Chemical Structure:



Molecular Weight: 100.1
Appearance: White or almost white powder.
Solubility: Practically insoluble in water.

Calcium carbonate is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

Suitable specifications have been provided for all packaging used. The primary packaging complies with the current regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCT

Pharmaceutical development
A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* dissolution profiles were provided for the proposed and reference products.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients.

No excipients of animal or human origin are used in the finished product.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product
A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specification
The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability
Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 24 months, with the storage conditions ‘Do not store above 25°C’, and ‘Store in original package in order to protect from moisture’, is acceptable.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of a marketing authorisation was recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction

This application was submitted under Regulation 54 of The Human Medicines Regulation 2012, as amended, as a well-established use application. No new non-clinical studies were submitted, as the data submitted for this application is in the form of literature references. The non-clinical overview provides an adequate review of the available published data on the non-clinical pharmacology, pharmacokinetics and toxicology of calcium carbonate and is satisfactory.

III.2 Pharmacology

Calcium carbonate is an inorganic salt primarily used to manage and treat low calcium conditions, GERD, CKD, and other indicated conditions. Calcium carbonate is classified as a calcium supplement, antacid, and phosphate binder. This activity outlines the significant indications, actions, and contraindications for calcium carbonate as a valuable agent in treating osteoporosis, hypothyroidism, rheumatoid arthritis, and many other conditions or disorders that lower serum calcium levels. As an antacid, calcium carbonate also increases gastrointestinal motility and initiates peristalsis. Calcium carbonate works in the small intestines as a phosphate binder and drug chelator. In individuals with hyperphosphatemia or overdose, calcium will bind to form an insoluble compound blocking dietary phosphate or excess drug absorption and excreting it in feces. Calcium carbonate, used as a calcium supplement, also acts in the small intestine by chelating with oxalate to prevent absorption and renal calculi formation. Lastly, calcium carbonate also works in the blood to treat or prevent negative calcium balance seen in low serum calcium conditions.

Calcium carbonate has three separate mechanisms of action that have pharmacologic effects. Calcium affects the stomach, small intestine, and blood.

As an antacid, calcium carbonate neutralizes gastric acid by acting as a buffer in the stomach's acidic environment. When $CaCO_3$ enters the stomach, it dissociates into ionized calcium (Ca) and a carbonate anion (CO). The carbonate anion will then bind to the free protons (H+) found in the stomach to increase the pH by decreasing the concentration of hydrogen ions. By increasing the pH in the stomach, pepsin, bile acids, and the toxins of Helicobacterpylori become inhibited. The inhibition of pepsin, an enzyme that can degrade tissue protein, and inhibition of bile acid helps reduce damage to and promote the healing of ulcers in the mucosal lining of the stomach and duodenum and injury to the esophagus caused by GERD. There is still some criticism regarding the ulcer-healing effects of calcium carbonate solely being due to its acid-neutralizing mechanism because calcium carbonate can cause acid rebound by increasing plasma gastrin levels and has been shown to increase prostaglandins PGE2 and PGF2 after long-term use that may explain an alternative mechanism to ulcer healing.

III.3 Pharmacokinetics

After oral administration, 18–40% of Ca is absorbed from the small intestine by active transport and passive diffusion. Active absorption of Ca is highly dependent on vitamin D, and vitamin D deficiency decreases the absorption of Ca. Absorption of Ca is dose dependent, with fractional absorption being highest when at doses up to 500 mg. Absorption of Ca is also dependent on pH (reduced in alkaline), body size, estrogen status, vitamin D status, age, and genetic polymorphisms. The absorption of Ca from $CaCO_3$ is increased when taken with food. Different Ca salts show different levels of absorption.

Skeletal Ca accounts for 99% of the Ca in the body. Of the remaining 1%, 40–45% is bound to proteins, primarily albumin. About 5–10% is complexed to phosphate, citrate, or other anions. Approximately 50% of Ca in the serum is in the physiologically active ionized form.

As an endogenously occurring substance, Ca is not metabolized in the traditional pharmacokinetic sense.

Unabsorbed Ca from the small intestine is excreted in the feces. Renal excretion depends largely on glomerular filtration and Ca tubular reabsorption with more than 98% of Ca reabsorbed from the glomerular filtrate, with only 2% lost as obligatory Ca loss. This process is regulated by active vitamin D and parathyroid hormone (PTH). Excess carbonate is excreted as CO_2 via respiration.

III.4 Toxicology

Different toxicity studies have been carried out with $CaCO_3$ in rats, mice, and cats. They have overall not demonstrated any evidence of toxicity attributable to $CaCO_3$.

The FDA recognizes calcium carbonate as a generally safe drug and food additive. A maximum dose of 8 to 10 g per day of calcium carbonate can be administered for short-term use. However, long-term use of over 2 grams can lead to adverse effects such as hypercalcemia, renal calculi, hypophosphatemia, and nephrotoxicity, especially in individuals with chronic kidney disease. Fetotoxicity has also been observed in pregnant women taking over 1500 mg/kg of body weight per day of calcium carbonate.

Total daily intake of Ca above 1500 mg has not demonstrated additional bone benefits, while daily intake above 2000 mg has been associated with increased risk of adverse effects, including hypercalcemia and kidney stones. However, intake of dietary Ca equivalent to 250 or 500 mg/kg bw/day in rats leaded to nephrocalcinosis, while in Beagle dogs at the same doses did not show any signs of nephrocalcinosis. Nephrocalcinosis was also not observed in a recent combined repeat dose oral toxicity/reproduction/ developmental toxicity screening study with $CaCO_3$ (having a particle size of 60–100 nm) carried out in Wistar rats at dose levels of up to 1000 mg/kg bw/day for up to 48 days. The only changes seen in this study were slight but statistically significant hematological and biochemical effects in males receiving 1000 mg/kg bw/day, and significant reductions in plasma phosphate levels in all male-treated groups. No evidence of toxicity was reported in a study in which mice were administered $CaCO_3$ (described as nano $CaCO_3$) by oral gavages at dose levels up to 1300 mg/kg bw/day.

III.5 Ecotoxicity/Environmental Risk Assessment

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is for a product containing an active substance of well-established use that will be used in place of existing products, an increase in environmental exposure is not anticipated following approval of the Marketing Authorisation for the proposed product.

III.6 Discussion on the non-clinical aspects

The grant of a marketing authorisation was recommended.

IV CLINICAL ASPECTS

IV.1 Introduction

This application was submitted under Regulation 54 of The Human Medicines Regulation 2012, as amended, as a well-established use application. No new non-clinical studies were submitted, as the data submitted for this application is in the form of literature references. The literature review provided is satisfactory.

IV.2 Pharmacokinetics

The non-clinical overview provides an adequate review of the available published data on the clinical pharmacokinetics of calcium carbonate.

IV.3 Pharmacodynamics

The non-clinical overview provides an adequate review of the available published data on the clinical pharmacodynamics of calcium carbonate.

IV.4 Clinical efficacy

The non-clinical overview provides an adequate review of the available published data on the clinical efficacy of calcium carbonate.

IV.5 Clinical safety

No new safety concerns data were submitted with this application and none were required. The literature review provided is satisfactory.

IV.6 Risk Management Plan (RMP)

The Applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The Applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

IV.7 Discussion on the clinical aspects

The grant of a marketing authorisation was recommended for this application.

V USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified from the literature. Extensive clinical experience with calcium carbonate is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, and in line with current guidelines.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**