SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calcium Carbonate 500mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 500 mg calcium carbonate equivalent to 200 mg calcium.

Also contains sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet

Light orange coloured, round tablet, plain on both sides, may contain specks.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of indigestion, heartburn, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, over indulgence in food and drink, indigestion during pregnancy, acid indigestion, and nervous indigestion.

4.2 Posology and method of administration

Tablets to be taken orally, sucked or chewed**.** Adults and children over 12 years:

Two tablets to be sucked or chewed as a single dose, preferably to be taken one hour after meals and before going to bed but also in between in case of heartburn or gastric pain. A maximum daily dose of 8 g calcium carbonate, corresponding to 16 tablets, a day must not be exceeded.

Children:

Not recommended for children under 12 years.

As with all antacids, if symptoms persist despite 14 days of continuous therapy, diagnostic measures are strongly recommended in order to rule out a more serious disease.

4.3 Contraindications

This tablet should not be administered to patients with:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcaemia and/or conditions resulting in hypercalcaemia
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphataemia

4.4 Special warnings and precautions for use

- Prolonged use should be avoided.
- The stated dose should not be exceeded. If, after 14 days of treatment, symptoms persist or only partly disappear, the patient should consult a doctor.
- Caution should be exercised in patients with mild to moderate impairment of renal function (See section 4.3 – contraindication in severe renal insufficiency). If this tablet is used in such patients, plasma calcium and phosphate levels should be regularly monitored.
- Long term use at high doses can result in undesirable effects such as hypercalcaemia and milk-alkali syndrome, especially in patients with renal insufficiency.
- This tablet should not be used in patients with hypercalciuria (see also section 4.3). Prolonged uses increases the risk of formation of renal calculi.
- This product should not be taken with large amounts of milk or dairy products.
- Patients with rare hereditary problems of sucrose intolerance, glucose- galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- Colour- Lake of Sunset Yellow may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

- It has been shown that antacids which contain calcium may form complexes with certain substances e.g. antibiotics (such as tetracyclines and quinolones) and cardiac glycosides (e.g. digoxin), biphosphonates, dolutegravir, levothyroxine, and eltrombopag, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.
- Calcium salts can also impede the absorption of phosphates, fluorides and iron-containing products.
- Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Therefore it is preferable to take the antacid separately from other drugs, allowing at least 4 hours before or after taking eltrombopag and a 1-2 hour interval for all other drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

No increased risks of congenital defects have been observed after the use of this product during pregnancy.

This medicine can be used during pregnancy if taken as instructed.

The maximum recommended daily dose should not be exceeded and should not be taken for more than 2 weeks. If symptoms persist or only partly disappear after 2 weeks, medical advice should be sought.

In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products (1 litre of milk contains up to 1.2 g elemental calcium).

Breastfeeding

Calcium carbonate is excreted in human milk, but at therapeutic doses of the product no effects on the breastfed newborns/infants are anticipated.

This medicine can be used during breastfeeding.

Fertility

There is no known evidence suggestive that at recommended dose this medicine has adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus an organisation according to CIOMS III categories of frequency is not possible.

Immune System Disorders:

Hypersensitivity reactions have very rarely been reported. Clinical symptoms may include rash, urticaria, pruritus, angioedema, difficulty in breathing and anaphylaxis.

Metabolism and Nutrition Disorders:

Especially in patients with impaired renal function, prolonged use of high doses can result in hypercalcaemia and alkalosis.

Gastrointestinal Disorders:

Nausea, vomiting, stomach discomfort, constipation and diarrhoea may occur.

Musculoskeletal and Connective Tissue Disorders:

Muscular weakness may occur.

Undesirable effects occurring in the context of milk-alkali syndrome (see 4.9):
Gastrointestinal Disorders:

Ageusia may occur in the context of milk-alkali syndrome.

General Disorders and Administration Site Conditions:

Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

Nervous System Disorders:

Headache may occur in the context of milk-alkali syndrome.

Renal and Urinary Disorders:

Azotemia may occur in the context of milk-alkali syndrome.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate can result in renal insufficiency, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, and constipation) and muscular weakness. In these cases, the intake of the product should be stopped and adequate fluid intake encouraged. In severe cases of over dosage (e.g. milk-alkali syndrome), a health care professional must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Classification: Antacids ATC codes: Calcium carbonate: A02AC01

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

$CaCO3 + 2HCl \rightarrow CaCl2 + H2O + CO2$

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.

5.2 Pharmacokinetic properties

A small amount of calcium may be absorbed, but in healthy subjects is usually rapidly excreted by the kidney. The soluble chloride produced by the reaction of calcium with gastric acid reacts, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3 Preclinical safety data

Preclinical studies on this medicine are not available. The available preclinical data on calcium carbonate based on studies of repeated dose toxicity, genotoxicity and or carcinogenic potential, and toxicity to reproduction revealed no specific hazard at therapeutic doses for humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Altered Tangerine Yellow
Sucrose
Potato Starch
Pregelatinised Starch
Sodium Saccharin
Trusil Orange ASV 030002 flavor (IFF)
Citric acid anhydrous
Purified talc
Magnesium Stearate
Trusil Orange ASV 030002 flavor contains:
Emulsifier (INS 414)
Maltodextrin
Natural flavouring Substances
Nature Identical flavouring Substances
Preservative (INS 211)
Antioxidant (INS 300)

Altered Tangerine Yellow contains:
Yellow Iron Oxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Do not store above 25°C. Store in original package in order to protect from moisture.

6.5 Nature and contents of container

Calcium Carbonate 500mg Chewable Tablets are available in aluminium foil- PVC film blisters or aluminium foil- PVC/PVDC film blister packs of 8's, 12's, 24's, 32's, 36's, 48's, 60's, 64's, 72's 84's, 96's or 120's along with leaflet inside the carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.
1st floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex,
HA1 2AX, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0190

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/12/2025

10 DATE OF REVISION OF THE TEXT

19/12/2025