

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Setlers Antacid Chewable Tablets Spearmint Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium carbonate 500mg

Excipients: Each tablet contains sucrose, glucose and sulphur dioxide

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets for oral administration.

A white tablet with a bevelled edge with “Setlers” engraved on both faces of the tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the symptomatic relief of acid indigestion, heartburn, flatulence and nausea.

4.2 Posology and method of administration

Adults, children over 12 years and elderly: one or two tablets to be sucked or chewed whenever required, up to a maximum of 8 tablets in any 24 hours.

Children aged 6 to under 12 years: one tablet to be sucked or chewed, up to a maximum of 4 tablets in any 24 hours. Not to be given to children under 6 years of age.

The normal adult dose can be taken by the elderly.

4.3. Contraindications

Patients on low phosphate diets, or receiving cardiac glycosides or with impaired hepatic or renal function.

Contraindicated in hypersensitivity to any of the ingredients

Contraindicated in hypercalcaemia, hypercalciuria (e.g. some forms of malignant disease), and calcium renal calculi.

4.4. Special warnings and precautions for use

Keep out of the reach and sight of children.
If symptoms persist consult your doctor or pharmacist.

Use with caution in diseases associated with hypercalcaemia such as sarcoidosis and some malignancies and in patients with a history of renal calculi.

This medicine contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

This medicine contains sulphur dioxide which may cause severe hypersensitivity reactions and bronchospasm.

4.5. Interaction with other medicinal products and other forms of interaction

Antacids of this type are known to decrease the absorption of concomitantly administered drugs due to absorption or delaying of gastric emptying or alkalisation of gastric juice. However, the activity of cardiac glycosides such as digoxin may be increased due to the presence of calcium.

Calcium may reduce the absorption of tetracyclines, eltrombopag, bisphosphonates, fluoride, oral iron, zinc, levothyroxine and some fluoroquinolones.

Thiazide diuretics may reduce urinary calcium excretion and cause hypercalcaemia. Vitamin D increases the gastrointestinal absorption of calcium and can cause hypercalcaemia. Plasma-calcium concentrations should be monitored in patients receiving calcium together with thiazide diuretics or Vitamin D.

Antacids may damage enteric coatings designed to prevent dissolution in the stomach.

Interactions may be minimised by ensuring that Setlers Antacid Chewable Tablets Spearmint Flavour are not taken at the same time as, nor within three hours of other medications.

4.6. Pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy, embryonal foetal development, parturition and postnatal development (see section 5.3). The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Calcium carbonate can cause gastro-intestinal disturbances including flatulence and constipation.

Calcium-containing antacids can induce rebound acid secretion; however, this is unlikely to be of clinical significance in normal use.

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 in the Google Play or Apple App Store

4.9. Overdose

Prolonged excessive ingestion of calcium carbonate may lead to hypercalcaemia. Patients with renal impairment are most at risk. Alkalosis is a potential but rare risk. There have been rare reports of the milk-alkali syndrome.

Symptoms of hypercalcaemia may include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi and, in severe cases, cardiac arrhythmias and coma.

Treatment should be aimed at lowering serum calcium levels and may include full hydration, monitoring of other electrolytes and other standard symptomatic and supportive measures.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Calcium carbonate is an antacid.

5.2. Pharmacokinetic properties

The product is formulated as a chewable tablet whose active has a local action in the gastrointestinal tract as an antacid.

5.3. Preclinical safety data

Calcium carbonate is a well established antacid active ingredient and considered to be non-toxic when administered orally at the recommended dosage. Therefore, single and repeat dose toxicity, foetal toxicity and fertility studies are not appropriate.

6.1 List of excipients

Icing Sugar (Sucrose)
Compressible Sugar (Sucrose and Maltodextrin)
Glucose
Maize starch
Spearmint flavour (Containing Sulphur Dioxide E220)
Talc
Magnesium stearate
Adipic acid.

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months

6.4. Special precautions for storage

None

6.5 Nature and contents of container

Coated paper lined foil roll wrapper containing 12 tablets per roll.
Three rolls are contained in a boxboard carton
Pack sizes: 36 tablets.

Blister pack consisting of PVC film sealed with an aluminium foil with heat-seal lacquer containing 12 tablets per blister.
Two blisters are contained in a boxboard carton.

Pack sizes: 24 tablets.

Not all pack sizes may be marketed.

6.6. Instructions for use/handling

None.

7. MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
HD7 5QH
United Kingdom.

8. MARKETING AUTHORISATION NUMBER(S)

PL 00240/0121

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th August 2003

10. DATE OF REVISION OF THE TEXT

13/06/2024