SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calcium Carbonate Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate Ph Eur 500 mg per tablet

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic treatment of conditions relating to stomach acidity including: heartburn (pyrosis), acid indigestion and flatulence due to these symptoms.

4.2 Posology and method of administration

Do not take for symptoms that persist for more than 7 days, unless advised by a doctor.

The Maximum Daily Dose (MDD) of this product is equivalent to 8g calcium carbonate (3.2g elemental calcium) for adults and children aged 12 and over; 3.5g calcium carbonate (1.4g elemental calcium) for pregnant women.

Adults and children aged 12 years and over: one or two tablets to be sucked or chewed as symptoms occur, up to as maximum of 16 tablets in any 24 hours, or as directed by a doctor.

Not to be given to children under 12 years of age.

Elderly: The normal adult dose can be taken by the elderly.
Pregnant women: one to two tablets to be sucked or chewed whenever required as symptoms occur, up to a maximum of 7 tablets in any 24 hours, or as directed by a doctor.

4.3 Contraindications

Contraindicated in patients with hypercalcaemia, hypercalciuria, or on a low-phosphate diet. Or those receiving cardiac glycosides or with impaired renal function.

Contraindicated in patients with a prior hypersensitivity reaction to calcium carbonate or any other ingredients of the preparation.

4.4 Special warnings and precautions for use

Prolonged use of higher than recommended doses may result in hypercalcaemia and milk alkali syndrome, particularly in patients with renal insufficiency.

If symptoms persist, consult your doctor.

Keep out of the sight and reach of children.

This product contains E110 (sunset yellow) and E124 (ponceau 4R red) which may cause allergic reactions.

This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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, such as bisphosphonates, tetracyclines and ciprofloxacin due to adsorption or delaying of gastric emptying or alkalinisation of gastric juice. This can be avoided by giving other drugs 2-3 hours before or after the administration of calcium carbonate on the advice of a doctor. However, the

activity of cardiac glycosides such as digoxin may be increased due to the presence of elevated calcium concentrations

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion.

4.6 Pregnancy and lactation

Pregnancy
Data on a large number of exposed pregnancies indicate no adverse effects of Calcium Carbonate Tablets on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available.

Breast Feeding
Calcium Carbonate Tablets are unlikely to present a risk to breastfeeding women at recommended doses.

4.7 Effects on ability to drive and use machines

Calcium carbonate is unlikely to cause any effects on the ability to drive and use machines.

4.8 Undesirable effects

Constipation, flatulence, nausea and belching are likely to occur rarely.

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.

4.9 Overdose

Overdose of calcium can lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death.

Treatment: withdrawal of the product and normal laxative measures. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium carbonate is an antacid.

5.2 Pharmacokinetic properties

Not applicable, since calcium carbonate acts locally in the gastrointestinal tract.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

TUMS Assorted Fruit Antacid tablets contain icing sugar, dextrose monohydrate, compressible sugar, starch, talc, magnesium stearate and anhydrous citric acid.

TUMS Lemon Flavour also contains lemon flavour J3790 and quinoline yellow lake (E104).

TUMS Orange Flavour also contains orange flavour 52.570 and sunset yellow lake (El10).

TUMS Blackcurrant Flavour also contains blackcurrant flavour J3045 and lynlake violet KLS/1/39/l (E124, E131).

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25ºC in a dry place.

6.5 Nature and contents of container

Roll: Paper/aluminium foil laminate roll pack containing 12 tablets per roll. Three rolls are contained in a boxboard carton with a cellophane overwrap or one roll contained in a single cavity PVC blister with cardboard backing.

Bottle: Polystyrene bottle, with a polyethylene cap, containing either 75 or 150 tablets.

As an occasional promtion a polypropylene roll-holder with a polypropylene cap may be shrink wrapped to the 36 tablets carton with 40 µ PVC sleeve.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
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Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0057

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th August 1988 / 26th August 1993 / 25th November 1998

10 DATE OF REVISION OF THE TEXT

24/08/2023