SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name><Strength> chewable tablets

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per tablet:

Calcium carbonate: 1500 mg equivalent to 600 mg of elemental calcium

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Chewable Tablets

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Calcium carbonate is a chewable tablet recommended as a supplementary source of calcium when normal requirements are high and in the correction of calcium deficiency in the diet. They can be used in osteoporosis therapy as an adjunct to more specific conventional treatments. calcium carbonate chewable tablets can be used as a phosphate binding agent in the management of renal failure.

* 1. Posology and method of administration

*Adults, elderly and children*

Dietary deficiency and as an adjunct in osteoporosis therapy; 2 chewable tablets per day, preferably one tablet each morning and evening.

For use in binding phosphate in the management of renal failure in patients on renal dialysis, the dose should be adjusted for the individual patient and is dependent on the serum phosphate level.

The tablets should be chewed, not swallowed whole and taken just prior to, during or immediately following a meal.

Method of administration

Oral

* 1. Contraindications

Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure untreated by renal dialysis. Hypersensitivity to any of the tablet ingredients.

Relative contraindications are osteoporosis due to prolonged immobilisation, renal stones, severe hypercalciuria.

* 1. Special warnings and precautions for use

Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully. Periodic checks of plasma calcium levels and urinary calcium excretion should be made in patients with mild to moderate renal failure or mild hypercalciuria.

Urinary calcium excretion should also be measured. In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalciuria.

With long-term treatment it is advisable to monitor serum and urinary calcium levels and kidney function and reduce or stop treatment temporarily if urinary calcium exceeds 7.5 mmol/24 hours.

Allowances should be made for calcium and vitamin D supplements from other sources.

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

* 1. Interaction with other medicinal products and other forms of interaction

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

The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with Vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium. Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone and tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

Calcium absorption is reduced in patients receiving systemic corticosteroid therapy. This should be taken into account when patients are receiving concomitant therapy.

* 1. Fertility, pregnancy and lactation

During pregnancy and lactation treatment with calcium carbonate should be under the direction of a physician. During pregnancy and lactation, requirements for calcium are increased but in deciding on the required supplementation allowances should be made for availability of these agents from other sources. If calcium carbonate and iron supplements are both required to be administered to the patient, they should be taken at different times (see Section 4.5).

* 1. Effects on ability to drive and use machines

None known.

* 1. Undesirable effects

The use of calcium supplements has, rarely, given rise to mild gastro- intestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrhoea.

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 Health Product Vigilance Center; HPVC, Thai FDA.

* 1. Overdose

Overdosage may cause gastro-intestinal disturbances but would not be expected to cause hypercalcaemia except in patients treated with excessive doses of vitamin D. Treatment should be aimed at lowering serum calcium levels through a high fluid intake and low calcium diet. In severe cases treatments with corticosteroid and other specialist treatment may be necessary. Alkalosis is a potential but rare risk.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Calcium carbonate is a well-established medicinal material and is used extensively for supplementation in deficiency states. Calcium carbonate is also widely used as an antacid.

* 1. Pharmacokinetic properties

The pharmacokinetic profiles of calcium and its salts are well known. Calcium carbonate is converted to calcium chloride by gastric acid. Calcium is absorbed to the extent of about 15-25% from the gastro- intestinal tract while the remainder reverts to insoluble calcium carbonate and calcium stearate and is excreted in the faeces.

* 1. Preclinical safety data

Calcium carbonate is a well-known and widely used material and has been used in clinical practice for many years. As such toxicity is only likely to occur in chronic overdosage where hypercalcaemia could result.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

<Regarding the approval>

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>