Product Information

Prescribing Information (Summary of Product Characteristics)

1.0 Name of the medicinal product

Calcium Carbonate Tablets USP 1250mg

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Each tablet contains: Calcium carbonate USP 1250 mg eq. to elemental calcium 500 mg. **"PRODUCT CONTAINS LACTOSE"**

Excipients with known effect:

Each tablet contains 37.503 mg Lactose

For the full list of excipients, see 6.1.

3.0 PHARMACEUTICAL FORM:

Tablets

Description: White to off white, elongated, biconvex, uncoated tablets having score line on one side.

1. CLINICAL PARTICULARS

2. Therapeutic Indications:

This product is a chewable tablet recommended as a supplementary source of calcium when normal requirements are high and in the correction 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 Tablets can be used as a phosphate binding agent in the management of renal failure.

3. Posology and method of administration:

Oral

The tablets should be taken just before, during or just after each meal. The tablets should be chewed or sucked. Dosage in hepatic impairment: No dose adjustment is required. Dosage in renal impairment: In patients with severe renal failure having a creatinine clearance of less than 25 ml/minute, dosage adjustments may be necessary dependent on serum calcium levels.

Adults and elderly: Adjunct to osteoporosis therapy: 2 to 3 tablets daily. Dietary deficiency: 2 to 3 tablets daily. Osteomalacia: 2 to 6 tablets daily. **Children:** Dietary deficiency: 2 to 3 tablets daily Phosphate Binder: Adults children and elderly: Dose as required by the individual patient depending on

serum phosphate level.

4. Contraindications

Severe hypercalcaemia and hypercalciuria, for example in hyperparathyroidism, vitamin D overdosage, decalcifying tumors such as plasmacytoma and skeletal metastases, in severe renal failure untreated by renal dialysis and in osteoporosis due to immobilisation. Nephrolithiasis Hypersensitivity to the active substance or to any of the excipients.

5. Special warnings and precautions for use

Patients with rare hereditary problems of fructose intolerance or sucrase-isomaltase insufficiency should not take this medicine. In renal insufficiency the tablets should be given only under controlled conditions for hyperphosphataemia. Caution should be exercised in patients with a history of renal calculi. During high dose therapy and especially during concomitant treatment with vitamin D and/or medications or nutrients (such as milk) containing calcium, there is a risk of hypercalcaemia with subsequent kidney function impairment or milk alkali syndrome. In these patients, serum calcium levels should be followed and renal function should be monitored.

Lactose

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose.

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

Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics. Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Calcium Carbonate Tablets. Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before, or four to six hours after, oral intake of calcium. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium. Patients should be monitored with regard to electrocardiogram (ECG) and

serum calcium levels. If a bisphosphonate or sodium fluoride is used concomitantly, this preparation should be administered at least three hours before the intake of Calcium Carbonate Tablets since gastrointestinal absorption may be reduced.

7.

The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours. The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or after intake of calcium. Oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble calcium salts. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

8. Pregnancy and lactation

The adequate daily intake (including food and supplementation) for normal pregnant and lactating women is 1000 – 1300 mg calcium. During pregnancy, the daily intake of calcium should not exceed 1500mg. Significant amounts of calcium are secreted in milk during lactation. Calcium Carbonate Tablets can be used during pregnancy in case of a calcium deficiency.

9. Effects on ability to drive and use machines

None known

10. Undesirable effects

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

11. 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.I In severe cases treatments with corticosteroid and other specialist treatment may be

necessary. Alkalosis is a potential but rare risk.

1. PHARMACOLOGICAL PROPERTIES

2. Pharmacodynamic properties

Pharmacotherapeutic group:

Supplement ATC code: A12A A04

An adequate intake of calcium is of importance during growth, pregnancy and breastfeeding.

3. 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.

4. 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

2. List of excipients:

Maize Starch BP, Microcrystalline Cellulose, Lactose, Sucrose, Purified Talc, Magnesium Stearate, Colloidal Anhydrous Silica, Sodium Starch Glycolate (Type A), Sodium Lauryl Sulfate, Purified Water.

“Product Contain Lactose”

3. Incompatibilities: Not applicable

4. Shelf life:3 years

5. Special precautions for storage:

Store at a temperature not exceeding 30 °C in a dry place. Protect from light.

6. Nature and contents of container:

Blister Pack (Blister Aluminium Foil, Clear PVDC Film).

7. Special precautions for disposal of a used medicinal:

Product or waste materials derived from such medicinal product and other handling of the product No special requirements.

7.0 MARKETING AUTHORISATION HOLDER:

Abacus Pharma (A) Ltd.

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8.0 MARKETING AUTHORISATION NUMBER:

TAN 22 HM 0330

9.0 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

21/09/2022

10.0 DATE OF LAST RENEWAL

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