Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cacit 500mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.25g Calcium Carbonate which when dissolved in water provides 500 mg of calcium as calcium citrate.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet
Round, flat white effervescent tablets with pink speckles and a distinctive orange odour and flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. Treatment of calcium deficiency states including osteomalacia, rickets and malabsorption syndromes affecting the upper gastrointestinal tract.

2. An adjunct to conventional therapy in the arrest or slowing down of bone demineralisation in osteoporosis.

3. As a therapeutic supplement during times when intake may be inadequate, particularly those associated with the increased demand of childhood, old age, pregnancy and lactation.

4.2 Posology and method of administration

The tablets must be dissolved in a glass of water and the solution should then be drunk immediately after complete dissolution of the tablets.

Adults and the Elderly
For calcium deficiency states and malabsorption, the dosage should be tailored to the individual patient’s needs. A dose of 1.0g to 2.5g per day is recommended.

For the treatment of osteoporosis a dose of up to 1.5g per day is normally required. In patients with adequate dietary calcium intake, 500mg daily may be sufficient.

Up to 1.5g of calcium per day is the recommended dosage for therapeutic supplementation.

Children
For calcium deficiency states including malabsorption and rickets, the dosage recommendation under adult dosage should be followed.

For therapeutic supplementation a dose of up to 1.0g per day is recommended.

4.3 Contraindications

Use in patients with calci-lithiasis, hypercalcaemia and hypercalciuria such as in hyperparathyroidism, hypervitaminosis D, neoplastic diseases with decalcification of bone and with prolonged immobilisation.

Use in the milk-alkali syndrome. Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

In mild hypercalciuria (exceeding 7.5 mmol/24 hours in adults or 0.12-0.15 mmol/kg/24 hours in children) or renal failure, or where there is evidence of stone formation in the urinary tract; adequate checks must be kept on urinary calcium excretion. If necessary the dosage should be reduced or calcium therapy discontinued.

Calcium salts should be used with caution in patients with impaired renal function, or with sarcoidosis.

The use of calcium salts should be accompanied by a careful surveillance to ensure maintenance of correct balance.

This product may induce hypophosphataemia.

This product contains a small amount of sorbitol (E420), patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration with vitamin D causes an increase in calcium absorption and plasma levels may continue to rise after stopping vitamin D therapy.

The effects of digoxin and other cardiac glycosides may be accentuated by calcium and toxicity may be produced, especially in combination with vitamin D.

Calcium salts reduce the absorption of some drugs, in particular tetracyclines. It is therefore recommended that administration of Cacit tablets be separated from these products by at least 3 hours.

Thiazide diuretics increase renal absorption of calcium, so the risk of hypercalcaemia should be considered.

Bisphosphonate, sodium fluoride: it is advisable to allow a two hour minimum period before taking Cacit (risk of reduction of the gastrointestinal absorption of bisphosphonate and sodium fluoride).

4.6 Pregnancy and lactation

Calcium supplements have been in wide use for many years without apparent ill consequence.

4.7 Effects on ability to drive and use machines

Cacit does not interfere with the ability to drive or use machines.

4.8 Undesirable effects

Gastrointestinal disturbances have been reported (e.g. nausea, abdominal pain, constipation, diarrhoea, flatulence and eructation). The colouring agent E110 can cause allergic-type reactions including asthma. Skin reactions such as pruritus, rash and urticaria have been reported. Allergy is more common in those people who are allergic to aspirin.

4.9 Overdose

The amount of calcium absorbed will depend on the individual’s calcium status. Deliberate overdosage is unlikely with

effervescent preparations and acute overdosage has not been reported. It might cause gastrointestinal disturbance 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, e.g. administration of oral phosphates.

Chronic overdose can lead to vascular and organ calcifications as a result of hypercalaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium is an essential element of tissues and plasma.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (anhydrous)
Sodium saccharin
Sodium cyclamate
Sunset yellow (E110)
Flavour (Contains Sorbitol (E420) and Mannitol (E421))

6.2 Incompatibilities

None known.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store below 30ºC. Keep the container tightly closed.

6.5 Nature and contents of container

Supplied in boxes of 76 tablets (4 polypropylene tubes with polyethylene stoppers each containing 19 tablets).

6.6 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 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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