SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cacit 500mg Effervescent Tablets
Calcium 500mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect
This medicine contains sunset yellow FCF (E110) and sorbitol (E420).
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Effervescent tablet

white-pink, round, biplane, faultless surface effervescent tablets

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. In the arrest or slowing down of bone demineralisation in osteoporosis, where other effective treatment is contra-indicated.

4. 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

Posology

Adults
For calcium deficiency states including malabsorption, the dosage should be tailored to the individual patient's needs. A dose of 1.0 g 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.

Special populations

Elderly people
The dose for adults can be applied for elderly patients.

Paediatric population
Calcium deficiency during the growth period:

- Children aged 6 to 10 years: 1 tablet daily (500 mg per day),
- Children aged over 10 years: 2 tablets daily (1 g per day).

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.

4.3 Contraindications

Hypercalcaemia (eg. due to hyperparathyroidism, hypervitaminosis D, decalcifying tumours, severe renal failure, bone metastases).
Severe hypercalciuria, calci-lithiasis and renal calculi.
Long term immobilisation accompanied by hypercalciuria and/or hypercalcaemia.
Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

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. The product should be administered with caution in patients with sarcoidosis because of possible increased metabolism of vitamin D to its active form. These patients should be monitored for serum and urinary calcium.

Calcium and alkali intake from other sources (food, enriched foods, or other medicinal products) should be monitored when calcium carbonate is prescribed.
When high calcium doses are given together with alkaline substances such as carbonate, there is a risk of milk-alkali syndrome. Calcium levels in serum should be monitored when administering high doses of calcium carbonate (see section 4.8 & 4.9).

During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics (see section 4.5) and in patients with high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function, treatment with calcium should be discontinued.

Sorbitol (E420)
This medicine contains 1.36 mg sorbitol per tablet. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Sunset Yellow FCF (E 110)
This medicine contains Sunset Yellow which may cause allergic reactions.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially ‘sodium-free’.

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 this medicine is 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 this medicine (risk of reduction of the gastrointestinal absorption of bisphosphonate and sodium fluoride).

Iron, zinc and strontium: Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after calcium.

4.6 Fertility, 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

This medicine has no or negligible influence on ability to drive and use machines.

4.8 Undesirable effects

System organ class	Frequency	Adverse drug reactions
Immune system disorders	Not known	Allergic-type reaction (including asthma) to the colouring agent E110. Allergy is more common in those people who are allergic to aspirin. Hypersensitivity reactions such as angio-oedema or laryngeal oedema
Metabolism and nutrition disorders	Rare	Hypercalciuria and, in rare cases, hypercalcaemia in cases of long-term treatment with high doses.
	Not known	Milk-alkali syndrome (frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment) Milk-alkali syndrome is usually reversible upon drug's discontinuation and specific treatment (saline diuresis, pamidronic acid).*
Gastrointestinal disorders	Rare	Mild gastrointestinal disturbances e.g. nausea, abdominal pain, diarrhoea, constipation, flatulence and eructation
Skin and subcutaneous tissue disorders	Rare	Skin reactions, such as pruritis, rash, and urticaria (especially urticaria in patients with a past history of allergy)

The frequencies of adverse events are ranked according to the following:

Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), not known (cannot be estimated from the available data).

*See section 4.4 or 4.9.

Other special populations

Patients with renal impairment: potential risk of hyperphosphatemia, nephrolithiasis and nephrocalcinosis (see section 4.4).

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 national reporting system:

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The amount of calcium absorbed will depend on the individuals 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. Symptoms of overdose may include nausea, vomiting, polydipsia, polyuria and constipation. Treatment should be aimed at lowering serum calcium levels, eg. administration of oral phosphates and rehydration.
Chronic overdoses can lead to vascular and organ calcifications as a result of hypercalcaemia.

In case of overdose, there is a risk of Milk-alkali syndrome (see sections 4.4 and 4.8).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Calcium, ATC code: A12A A04

Pharmacodynamic effects

Calcium is an essential element of tissues and plasma.

5.2 Pharmacokinetic properties

Absorption
When the tablets are added to water, insoluble calcium carbonate is converted into absorbable calcium citrate.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

Sodium saccharin

Sodium cyclamate

Sunset Yellow FCF (E110) and flavour

6.2 Incompatibilities

None

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Keep the tube tightly closed in order to protect from moisture.

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

To be dissolved in water before administration as described in Section 4.2

Any unused medicinal product or waste material should be disposed in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20075/0669

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of latest renewal: 28 October 2005

10 DATE OF REVISION OF THE TEXT

09/06/2023