

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

B-CAL (chew tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each B-CAL chew tablet contains:

| Ingredients (Approved Name) | Per tablet |
|-------------------------------------|------------|
| Calcium (Calcium Carbonate 1250 mg) | 500 mg |

Contains sugar: fructose 0,5 g/tablet

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

B-CAL chew tablet is a thick round white to off-white tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

4.2 Posology and method of administration

Chew 1 – 2 tablets daily with meals, or as recommended by a healthcare provider. The dose required is dependent on dietary calcium intake.

If taking 2 tablets per day, it is recommended to split the dose by at least 4 hours to ensure maximum absorption.

The recommended daily dose should not be exceeded.

4.3 Contraindications

Hypersensitivity to any of the ingredients including the excipients. Patients with hypercalcaemia, hypercalciuria, renal impairment, renal calculi or sarcoidosis.

Patients with renal osteodystrophy with hyperphosphatemia.

4.4 Special warnings and precautions for use

- Calcium supplementation should be avoided in cases of hypercalcaemia and hypercalciuria (see **CONTRAINDICATIONS**).
- Calcium supplementation should be used with caution in patients with hypophosphatemia or hyperphosphatemia.
- Use with caution in patients with heart disease.
- B-CAL chew tablets contain sugar which may have an effect on the control of blood sugar in patients with *Diabetes Mellitus*.
- Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, should not take B-CAL.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **B-CAL**.

The following interactions are noted on monographs of the active ingredients:

Calcium-channel blockers: calcium supplements may reduce the effects of calcium channel blockers.

Digoxin: administration of high doses of calcium increases the risk of cardiac arrhythmias.

Estrogen: concurrent use may cause hypercalcaemia.

Thiazide diuretics: thiazides reduce calcium excretion by the kidneys.

Thyroid medicines: Calcium can interfere with thyroid hormone replacement treatment. Administration of calcium supplements and thyroid medications should be separated by at least 4 hours.

Calcium can chelate and prevent the absorption of some medicines such as tetracyclines, quinolones, bisphosphonates, anti-retrovirals, levothyroxine and verapamil. Doses should be separated by at least 4 hours.

4.6 Fertility, pregnancy and lactation

B-CAL tablets are suitable for use during pregnancy and lactation at the recommended dose and at the discretion of a healthcare professional.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects include gastrointestinal discomfort (constipation, diarrhoea, flatulence, nausea, belching and stomach upset. Prolonged use of high doses of calcium (approx. 20 g/day) can cause kidney stones.

4.9 Overdose

High doses can cause nausea, vomiting, diarrhoea and symptomatic hypercalcaemia, including hypotension and bradycardia. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.7 Minerals

5.2 PHARMACOLOGICAL ACTION

Calcium is an essential nutrient for the development of healthy bones and teeth.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, maize starch, Trusil orange. Contains sugar: Fructose 0,5 g/tablet.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

B-CAL tablets are packed in plastic containers of 30 or 100 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

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