

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

B-CAL (chew tablets)

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per tablet
Calcium (from 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:

- Contributes to the development and maintenance of bones and teeth.
- Contributes to normal muscle function.
- Contributes to normal blood clotting.
- Contributes to normal energy-yielding metabolism.
- Contributes to normal neurotransmission.
- Contributes to normal function of digestive enzymes.
- Has a role in the process of cell division and specialisation.
- Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.
- A factor in the maintenance of good health.

### 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

September 2020