

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

B-CAL-K2 (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients (Approved Name)	Per tablet
Calcium (Calcium Carbonate)	500 mg
Magnesium (Magnesium Oxide)	100 mg
Vitamin C (Ascorbic Acid)	60 mg
Vitamin K2 (Vitamin K2)	45 ug
Vitamin D3 (Vitamin D3)	1000IU

Sugar free

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

B-CAL-K2 is an off-white oval 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. Contributes to the development and maintenance of healthy bones and teeth.

4.2 Posology and method of administration

Adults and children 9 years and older: Take 1 tablet daily with a meal, or as recommended by a healthcare provider. The dose required is dependent on your dietary calcium intake. Do not exceed the recommended daily dose.

4.3 Contraindications

Hypersensitivity to any of the ingredients within **B-CAL-K2**, including any excipients.

Do not use in patients with:

- hypercalcaemia, hypercalciuria, renal impairment or renal calculi
- Sarcoidosis

Do not use in patients under the age of 9 years.

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 a blood clotting disorder (see **Interactions with other medicines and other forms of interaction**)
- Use with caution in patients with heart disease.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on B-CAL-K2. The following interactions are noted on monographs of the active ingredients:

Anticoagulants/Antiplatelets: All forms of vitamin K may interact with blood thinning medicines such as warfarin.

Antidiabetics (Sulfonylureas): concomitant administration with vitamin k/magnesium may enhance absorption and effect of sulfonylureas.

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. Magnesium may reduce the absorption of digoxin and thereby reduce its therapeutic effects.

Estrogen: concurrent use may cause hypercalcaemia.

Gabapentin: concurrent use with magnesium reduces the absorption of gabapentin.

Levodopa/Carbidopa: magnesium may reduce the effectiveness of levodopa/carbidopa if taken together.

Potassium sparing diuretics: magnesium levels may increase with concurrent use.

Thiazide diuretics: thiazides reduce calcium excretion by the kidneys.

Thyroid medicines: Calcium can interfere with thyroid hormone replacement treatment. Separate the administration of calcium supplements and thyroid medications 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-K2 is suitable for use during pregnancy and lactation at the recommended doses 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 (abdominal pain/upset, constipation, diarrhoea, flatulence, nausea, belching) and skin lesions.

4.9 Overdose

High doses of magnesium can cause diarrhoea and symptomatic hypermagnesemia including hypotension, nausea, vomiting, and bradycardia.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

- Calcium, magnesium and vitamin D are essential nutrients for the development of healthy bones and teeth.
- Magnesium contributes to normal muscle function and normal electrolyte balance.
- Vitamin C contributes to normal collagen formation for bone and cartilage function and contributes to the protection of cells from oxidative stress.
- Vitamin D helps in the absorption and use of calcium in the body, and to the maintenance of normal muscle function.
- Vitamin K2 is a fat-soluble vitamin which contributes to bone and cardiovascular health, as it helps regulate the transport and distribution of calcium in the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium, copovidone, colloidal silica, flexicoat protect white, magnesium stearate, microcrystalline cellulose. SUGAR FREE

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.

Store blisters in carton to protect from sunlight and moisture. KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

B-CAL-K2 is packed in blisters of 10. Each carton contains 3 blisters.

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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