PROFESSIONAL INFORMATION

SCHEDULING STATUS
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1 NAME OF THE MEDICINE

B-CAL-K2 (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per tablet
Calcium (from calcium carbonate)	500 mg
Magnesium (from magnesium oxide)	100 mg
Vitamin C (as ascorbic acid)	60 mg
Vitamin K2 (as K2 Vital)	45 ug
Vitamin D3 (as cholecalciferol)	1000IU

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. **B-CAL-K2** helps with 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.
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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:

- Contributes to the development and maintenance of bones and teeth.
- Contributes to normal muscle function.
- Contributes to normal energy-yielding metabolism.
- 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.

Magnesium:

- Contributes to normal energy -yielding metabolism.
- Contributes to normal electrolyte balance.
- Contributes to a reduction of tiredness and fatigue.
- Contributes to the maintenance of normal muscle function.
- Contributes to normal protein synthesis.
- Has a role in the process of cell division.
- Contributes to the maintenance of normal bones.
- Contributes to the maintenance of normal teeth.
- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.
- A factor in the maintenance of good health.

Vitamin C:

- Contributes to cell protection from free radical damage and oxidative stress.
- Contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin and teeth.
- Contributes to normal energy-yielding metabolism.
- Contributes to the normal function of the immune system.
- Contributes to the reduction of tiredness and fatigue.
- Helps in connective tissue formation.
- Contributes to wound healing.
- An antioxidant for the maintenance of good health.
- A factor in the maintenance of good health.

Vitamin K2:

- Contributes to the maintenance of normal bones
- A factor in the maintenance of good health

Vitamin D:

- Helps in the absorption and use of calcium and phosphorus.
- Contributes to normal cell division.
- Contributes to normal blood calcium levels.
- Contributes to the maintenance and development of strong bones and teeth.
- Contributes to the maintenance of normal muscle function.
- Contributes to the normal function of the immune system.
- Has a role in the process of cell division.
- Calcium intake, when combined with sufficient Vitamin D, a healthy diet and exercise, may reduce the risk of developing osteoporosis.
- A factor in the maintenance of good health.

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 tablets each, with 3 or 9 blisters (30 or 90 tablets) in a carton.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
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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 2022