

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

B-CAL-ULTRA (Swallow Tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients (Approved Name)	Per tablet
Calcium (Calcium Carbonate)	500 mg
Magnesium (Magnesium Oxide)	85 mg
Vitamin C (Ascorbic Acid 90 %)	60 mg
Vitamin B6 (Pyridoxine hydrochloride)	24 mg
Zinc (Zinc amino acid chelate 10 %)	15 mg
Glycine (Zinc glycinate 10%)	5,274 mg
Manganese (Manganese amino acid chelate 10 %)	2 mg
Copper (Copper glycinate 10 %)	1 mg
Glycine (Copper glycinate 10 %)	0,355 mg
Folic acid	490 ug
Selenium (Selenium glycinate 20 %)	37 ug
Glycine (Selenium glycinate 20 %)	12,22 ug
Molybdenum (Molybdenum glycinate 0,2 %)	25 ug
Glycine (Molybdenum glycinate 0,2%)	5,9 ug
Vitamin B12 (Vitamin B12 1 %)	24 ug
Vitamin D (Vitamin D3 100000 IU/g)	400IU

Sugar free

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

B-CAL-ULTRA is a light purple 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.

4.2 Posology and method of administration

Adults: Take 1 tablet daily with food, or as recommended by a healthcare provider. The dose required is dependent on dietary calcium intake.

4.3 Contraindications

Hypersensitivity to any of the ingredients including any 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. Use in patients under the age of 18 years is at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on B-CAL-ULTRA. The following are noted in monographs of the active ingredients:

Anticoagulants/Antiplatelets: concomitant use with magnesium could increase the risk of bleeding.

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.

Sulfonylureas: concomitant administration with magnesium may enhance absorption and effect of sulfonylureas.

Thiazide diuretics: thiazides reduce calcium excretion by the kidneys.

Thyroid medicines: Calcium can interfere with thyroid hormone replacement treatment. Separate calcium 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

The safety of B-CAL-ULTRA swallow tablets during pregnancy and lactation has not been established.

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).

4.9 Overdose

High doses can cause nausea, vomiting, diarrhoea and symptomatic hypermagnesemia and hypercalcaemia, including hypotension 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. Vitamin D helps in the absorption of calcium.
- Magnesium contributes to normal muscle function and normal electrolyte balance.
- The B Vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Vitamin C is an antioxidant for the maintenance of good health. It contributes to cell protection from free radical damage, helps in the development and maintenance of bones, cartilage, teeth and gums and helps with connective tissue formation.
- Copper and Zinc contribute to immune function.
- Manganese, Molybdenum and Selenium protect cells from oxidative stress.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copovidone, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Coating: flexicoat light purple, castor oil, shellac.
SUGAR FREE

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-ULTRA swallow tablet is packed in plastic containers with 30 or 60 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