PROFESSIONAL INFORMATION

SCHEDULING STATUS
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1 NAME OF THE MEDICINE

B-CAL-ULTRA (Swallow Tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per tablet
Calcium (from calcium carbonate)	500 mg
Magnesium (from magnesium oxide)	85 mg
Vitamin C (as ascorbic acid)	60 mg
Vitamin B6 (as pyridoxine hydrochloride)	24 mg
Zinc (from zinc amino acid chelate 10 %) Glycine (from zinc glycinate 10%)	15 mg 5,274 mg
Manganese (from manganese bisglycinate 10 %) Glycine (from manganese bisglycinate 10 %)	2 mg 0,739 mg
Copper (from copper glycinate 10 %) Glycine (from copper glycinate 10 %)	1 mg 0,355 mg
Folic acid	490 ug
Selenium (from selenium glycinate 20 %) Glycine (from selenium glycinate 20 %)	37 ug 12,22 ug
Molybdenum (from molybdenum glycinate 0,2 %) Glycine (from molybdenum glycinate 0,2%)	25 ug 5,9 ug
Vitamin B12 (as cyanocobalamin)	24 ug
Vitamin D (as cholecalciferol)	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:
- 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.

Magnesium:
- Contributes to normal energy -yielding metabolism.
- Contributes to normal functioning of the nervous system.
- 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.
- Contributes to normal psychological function.
- 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 iron absorption from food.
- Helps to metabolise fats and proteins.
- 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 normal functioning of the nervous system.
- Contributes to normal psychological function.
- 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.

Vitamins B6 and B12:
- Helps to metabolise carbohydrates, protein and fats.
- Plays a role in the process of cell division.
- Contributes to the normal functioning of the nervous system.
- Contributes to normal psychological function.
- Contributes to normal cysteine synthesis.
- Contributes to normal homocysteine metabolism.
- Contributes to normal red blood cell formation
- Contributes to the normal function of the immune function
- Contributes to the reduction of tiredness and fatigue
- Contributes to the regulation of hormonal activity
- Contributes to tissue formation
- A factor in the maintenance of good health

Zinc:
- Contributes to the maintenance of immune function.
- Contributes to the maintenance of normal skin, nails and hair.
- Contributes to normal acid-base metabolism.
- Contributes to normal cognitive function.
- Contributes to normal DNA synthesis.
- Contributes to normal metabolism of Vitamin A.
- Contributes to the maintenance of normal bones.
- Contributes to the maintenance of normal vision.
- Contributes to cell protection from free radical damage and oxidative stress.

Manganese:
- Contributes to the development and maintenance of normal bones.
- Contributes to the protection of cells from oxidative stress

Copper:
- Contributes to normal iron transport and metabolism.
- Contributes to the protection of cells from oxidative stress.

Folic acid:
- Helps the body to metabolise proteins.
- Helps to form red blood cells.

Selenium:
- An antioxidant for the maintenance of good health.
- Contributes to the protection of cells from oxidative stress.
- Contributes to the maintenance of normal skin, nails and hair.
- Contributes to the normal function of the immune system.
- Contributes to normal thyroid function.

Molybdenum:
- Contributes to normal sulphur amino acid metabolism.
- Helps the body to metabolise proteins.

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
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

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 2020