

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

B-CAL-DM (Swallow Tablet)

B-CAL-DM (Chew Tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each B-CAL-DM tablet and chew tablet contains:

Ingredients	Per tablet
Calcium (Calcium Carbonate 1250 mg)	500 mg
Magnesium (Swallow tablet: Magnesium Carbonate; Chew tablet: Magnesium Oxide)	125 mg
Vitamin D3 (Cholecalciferol)	400IU (10 ug)

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

B-CAL-DM swallow tablet is an oblong, yellow, coated tablet.

B-CAL-DM chew tablet is a 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. Contributes to the development and maintenance of bones and teeth.

4.2 Posology and method of administration

Adults and children 9 years and older: 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 or 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-DM 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-DM chew tablets**.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **B-CAL-DM**. The following interactions are noted on 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 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, levohydroxine and verapamil. Doses should be separated by at least 4 hours.

4.6 Fertility, pregnancy and lactation

B-CAL-DM swallow tablets are suitable for use during pregnancy and lactation at the recommended dose and at the discretion of the treating 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).

4.9 Overdose

High doses can cause nausea, vomiting, diarrhoea and symptomatic hypermagnesaemia 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

B-CAL-DM swallow tablets: beeswax, colloidal silica, magnesium stearate, maize starch, maltodextrin, opadry yellow, povidone, silicon dioxide, sodium starch glycolate, stearic acid.
SUGAR FREE

B-CAL-DM chew tablets: copovidone, crosscarmellose sodium, magnesium stearate, talc, trusil orange flavour. Contains sugar: Glucose 0,25 g/tablet; Isomalt 0,33 g/tablet Contains sweetener: Sucralose 2,4 mg/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-DM swallow tablet is packed in plastic containers with 30, 60 or 100 tablets.

B-CAL-DM chew tablet is 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 To be allocated

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

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