



PROFESSIONAL INFORMATION

Scheduling Status: **SO**

1. Proprietary Name

Cal-Mag

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
Magnesium (as <i>S. cerevisiae</i>) Providing elemental Magnesium 30 mg	150 mg
Calcium (as AlgaeCal®) Providing elemental Calcium 62 mg	220 mg

2.2 Sugar Free

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical form

Size 0 capsules containing light brown free-flowing powder.

4. Clinical Information

4.1 Indications for Use

Where a deficiency in the active ingredients may exist.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 2 capsules daily.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Not recommended for individuals who are under the age of 18. Women who are pregnant or breastfeeding should consult a relevant healthcare practitioner before use. Do not exceed the recommended daily dose.

4.5 Interactions

S. cerevisiae: Major risk of interactions with MAOIs. Moderate risk of interactions with antidiabetic drugs and lithium.

Magnesium: Moderate risk of interactions with aminoglycoside antibiotics, antacids, bisphosphonates, calcium channel blockers, digoxin, ketamine, quinolone antibiotics, skeletal muscle relaxants, sulfonylureas, and tetracycline antibiotics. Major risk of interactions with levodopa/carbidopa.



4.6 Pregnancy and Lactation

The safety in pregnancy and breastfeeding has not been established.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

Mild gastrointestinal disturbances may occur, such as nausea, diarrhoea, constipation, indigestion, bloating, metallic taste in the mouth, and flatulence.

5 Pharmacological Classification:

Category and Class D: 34.12 Multiple Substance Formulation.

Complementary Medicine.

6 Pharmacokinetic Properties

Magnesium

Absorption: Parathyroid hormone and Vitamin D are both required for absorption of magnesium. A third of the required dietary requirement is absorbed in the GIT. The amount/efficiency of the magnesium absorption depends on the magnesium stores in the body. The absorption from supplements varies from 38% to 65% depending on the body stores. Plasma concentration peaks at 4 hours after consumption of a dose of magnesium. The dosage form of magnesium may contribute to the absorption of magnesium. Magnesium is well absorbed from any food form. When magnesium intake is increased the fractional absorption usually decreases. The bioavailability of magnesium appears to be the best in magnesium chloride and magnesium lactate. Magnesium oxide and magnesium sulphate only contribute to about 4% bioavailability.

Distribution: The skeleton and soft tissue contain about 25 g of magnesium. Two thirds of the skeletal magnesium is bound to the bone and therefore is not available as a magnesium source, a third of the skeletal magnesium is a reservoir to maintain the extracellular magnesium concentrations and is at the surface of the bone, this is about 1% of the total body concentration of magnesium, 55% is ionized in the plasma, 30% is bound to plasma proteins and 15% complexed anions.

Magnesium undergoes a reabsorption filtration process. The concentration of magnesium in the proximal tube is 1.5 times of the concentration of the glomerular filtrate, and 20% to 30% is reabsorbed. The loop of Henle reabsorbs about 65% of filtered magnesium. Magnesium and calcium compete for transport in the thick ascending limb of Henle at the basolateral surface. Magnesium reabsorption is dependent on the parathyroid hormones, plasma magnesium, and calcium level alterations and the use of loop diuretics.

Excretion: The kidneys excrete between 3% and 5% filtered magnesium. Over a 24-hour period, between 10 to 5000 mg magnesium is excreted. Urinary magnesium and pH modulate urinary calcium excretion.

Calcium

Absorption: Calcium absorption is affected by several factors. It varies based on age environmental and dietary conditions. In healthy premenopausal females, the proportion of dietary calcium absorbed varies from 10% to 60%, and is directly linked to body mass index, dietary fat, and serum Vit D level. The proportion of dietary calcium absorbed is inversely correlated to dietary calcium intake, fibre and alcohol intake and exercise. Low calcium absorption can be linked to low-fat, high-fibre diet, possibly due to the rate of transit in the intestines. Protein may also have an impact on calcium absorption.

With weight loss greater than 5%, a greater loss of bone mass and increased risk of bone fracture is a possibility.

Calcium absorption during weight loss seems to decrease. Taking calcium supplements during weight loss seems to suppress the increased bone resorption. Calcium has a threshold absorption. Above threshold increased calcium intake has no effect, below threshold it results in increased response. It is recommended that calcium be taken at 500 mg doses or less. Taking calcium with food improves the absorption of calcium.



Calcium absorption seems to improve from early to late pregnancy and decreases in early lactation and then increase at weaning.	83
Distribution: Bones and teeth contain more than 99% of calcium in the body. Calcium is mainly present in the bone as hydroxyapatite. The blood, extracellular fluid muscle and other tissue also contain calcium. The reserve source of calcium that is present in the bone can be mobilized to maintain extracellular calcium concentration.	84
Excretion: Calcium is excreted in the urine and faeces. During late pregnancy and lactation the excretion in the urine is decreased. Calcium supplementation increase urinary excretion. Calcium excretion is increased with individuals affected by osteoporosis. Calcium excretion in urine is decreased when intake of calcium is low and intake of protein is high.	85
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7 Pharmaceutical Information	93
7.1 List of Excipients	94
Milled rice flour, vegetarian capsules.	95
7.2 Incompatibilities	96
None	97
7.3 Shelf Life	98
24 months from date of manufacture	99
7.4 Storage	100
Store in a cool dry place, between 15°C -25°C. Store in original container.	101
7.5 Presentation	102
60 white size 0 capsules packed in a 300 ml cylindrical white container with a lid and packaged.	103
7.6 Disposal and handling of product	104
All unused medication should be disposed of in accordance with local regulatory authority.	105
8. Holder of certificate of registration	106
FoodGrown™©	107
371 Angus Crescent	108
Northlands Business Park	109
North Riding	110
Gauteng	111
South Africa	112
9. Registration Number	113
Still to be allocated	114
10. Date of first authorisation	115
Still to be allocated	116
11. Date of review	117
New	118
12. Reference: https://naturalmedicines.therapeuticresearch.com/	119
	120
APPLICANT DETAILS:	121
FoodGrown™©	122
371 Angus Crescent	123
Northlands Business Park	124

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