



PROFESSIONAL INFORMATION

Scheduling Status:

SO

1. Proprietary Name

Magnesium

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
S. cerevisiae enriched with Magnesium oxide. (Providing elemental Magnesium)	500 mg

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical form

White size 0 capsules containing light tan brown free-flowing powder.

4. Clinical Information

4.1 Indications for Use

Indicated to supplement magnesium intake or for individuals with a magnesium deficiency.

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. Take with a meal.

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, such as nausea, diarrhoea, constipation, indigestion, bloating, metallic taste in the mouth, and flatulence.

5 Pharmacological Classification

Category D: 34.7 Minerals.

Complementary Medicine.

6 Pharmacokinetic Properties

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, 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 hormone, 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.

7 Pharmaceutical Information

7.1 List of Excipients

Milled rice flour, vegetarian capsules.

7.2 Incompatibilities

None.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

60 white size 0 capsules packed in a 300 ml cylindrical white container with a lid and packaged.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©

371 Angus Crescent

Northlands Business Park

North Riding

Gauteng

South Africa

9. Registration Number

Still to be allocated

10. Date of first authorisation

Still to be allocated

11. Date of review

New

12. Reference: <https://naturalmedicines.therapeuticresearch.com/>

APPLICANT DETAILS:

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