

PROFESSIONAL INFORMATION

Complementary Medicine, Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use

SCHEDULING STATUS: S0

NAME OF THE MEDICINE: ALPHA Magnesium Effervescent Tablets 10's and 30'S

QUALITATIVE AND QUANTITATIVE COMPOSITION:

☒ **ACTIVE INGREDIENTS:**

Each effervescent tablet contains:	mg	%NRV
Magnesium (Amino Acid Chelate)	172	41
Providing Magnesium (elemental)	34.4	
Vitamin C (Ascorbic acid)	150	150

*NRV (Nutrient Reference Values)

- ☒ **Contains Sugars:** Mannitol 450 mg per effervescent tablet
- ☒ **Contains Sweeteners:** Sucralose 17 mg per effervescent tablet
- ☒ **Excipients:** Vanilla Flavour (25 mg), Raspberry Flavour (200 mg), Carmosine Colouring (E122) (2.5mg), Ponceau Colouring (E124) (2,5 mg) and a proprietary effervescent blend (2987 mg).
- ☒ **The effervescent blend** contains sodium bicarbonate, citric acid, polyethylene glycol and Silicon Dioxide.

PHARMACEUTICAL FORM

- ☒ Effervescent Tablet
- ☒ Speckled pale pink, flat, round 25 mm

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

ALPHA Magnesium contains Vitamin C and Magnesium Amino Acid Chelate (AAC) as active ingredients. Magnesium has been shown to be a cofactor in more than 300 enzyme processes in the human body. It is an essential cofactor in the production and utilization of cellular energy and plays a vital role in a multitude of metabolic processes, many of which are at the root of chronic illnesses and conditions such as metabolic syndrome and fat metabolism (including cholesterol). Magnesium is essential for the conversion of Vitamin B1 and B6 into their active forms, the conversion of L-Dopa to Dopamine as well as the metabolism of dietary proteins and the production and utilisation of DNA and RNA. Magnesium in the AAC form is highly bioavailable.

Vitamin C (Ascorbic Acid) is a water-soluble anti-oxidant with particular benefits in supporting the immune system

ALPHA Magnesium may be used as a daily maintenance supplement and may help in the prevention and treatment of:

- ☒ Magnesium or Vitamin C deficiency and related conditions
- ☒ Healthy bones, teeth and structural growth
- ☒ Optimal muscle function
- ☒ Cellular energy production
- ☒ Cardiovascular health, including hypertension, angina, arrhythmias, congestive heart failure
- ☒ Immune support

- ☒ Nervous conditions (including migraine, neuralgia, insomnia, concentration) and stress

- ☒ Metabolic support for intestines, liver, kidney, blood fats and blood glucose, obesity

- ☒ May improve lung function, vision, and reproductive function and prevent loss of hearing

Posology and Method of Administration

Adults and Children over 9 years of age: One effervescent tablet daily dissolved in a glass of water, after a meal.

Do not exceed the recommended dosage without consulting a relevant healthcare provider.

CONTRAINDICATIONS

Hypersensitivity to any of the active substances or to any of the excipients.

Children under 9 years of age.

Renal impairment, neuromuscular disease, acute dehydration or gastric lesions and disorders.

Vitamin C supplementation is contraindicated in blood disorders like thalassemia, G6PD deficiency, sickle cell disease, and hemochromatosis. Avoid taking supplements immediately before or following angioplasty. Diabetic patients should take vitamin C supplements with care as it raises blood sugar levels.

See “SPECIAL WARNINGS AND PRECAUTIONS FOR USE”

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Certain anti-biotics and antivirals such as amongst others the Tetracyclines and medicines used in the treatment of HIV, have been shown to have reduced serum levels if used in conjunction with bivalent cations such as Magnesium. The mechanism of this interaction is not known. It is therefore prudent to use **ALPHA Magnesium** two hours **before** or six hours **after** other medications.

Care should be taken in patients using Vitamin D preparations or supplementation as this may lead to hypermagnesemia, particularly in dialysis patients due to potentially additive pharmacological effects. This may in turn lead to adynamic bone disease. If signs of hypermagnesemia develop, stop the use of **ALPHA Magnesium**.

In patients requiring Calcium supplementation, the ratio of Calcium to Magnesium taken should be 2:1 to prevent depletion of Calcium as Magnesium competes with Calcium for absorption in the intestines.

See “INTERACTIONS”.

Patients suffering from Hemochromatosis should not use **ALPHA Magnesium** due to the ability of Vitamin C to increase absorption of iron from the intestinal tract.

In general, health supplements should not be dispensed to any children younger than seven (7) months old unless where supplementation is medically warranted.

INTERACTIONS

Medicine interactions

The efficacy of certain Anti-biotics and Anti-virals may be negatively affected by the presence of Magnesium (AAC). **ALPHA Magnesium** should be taken 2 hours **BEFORE** or 6 hours **AFTER** such medications.

Patients regularly using high doses of Magnesium-based laxatives and antacids in addition to **ALPHA Magnesium** should be carefully monitored for signs of hypermagnesemia.

See „OVERDOSE“

Other Interactions

Vitamin D from food or supplements may increase the serum levels of Magnesium.

The intestinal absorption of Calcium, Phosphorous and Manganese may be reduced in the presence of Magnesium. Conversely, a high intake of Phosphorous may inhibit the uptake of Magnesium.

Ascorbic Acid may increase absorption of Iron from the intestine.

FERTILITY, PREGNANCY AND LACTATION

ALPHA Magnesium has not been tested for safety during Pregnancy and Lactation

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

ALPHA Magnesium has no or negligible influence on the ability to drive and use machines

UNDESIRABLE EFFECTS

ALPHA Magnesium may have some side-effects although none have been reported to date. **ALPHA Magnesium** is generally well tolerated.

Immune system disorder

Frequency not known

Hypersensitivity

Gastrointestinal disorder

Frequency not known

Diarrhoea, nausea, gastrointestinal discomfort

Renal and urinary disorder

Frequency not known

Renal impairment

Musculoskeletal and connective tissue disorder

Frequency not known

Muscle cramps

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

OVERDOSE

An overdose of Magnesium is extremely rare, as excess Magnesium is usually excreted via the urine or faeces. However, in the case of a low Calcium intake or in the case of chronic Renal disease (including dialysis), hypermagnesemia may result.

Symptoms of Hypermagnesemia may include gastrointestinal symptoms, muscle weakness, arrhythmias and hypotension, breathing difficulty, depression and loss of consciousness.

If overdose of Magnesium is suspected, intake should be stopped, and a health care professional consulted for treatment of clinical manifestations.

Magnesium may be counteracted by injection of calcium gluconate or removed by the application of intravenous fluids or renal dialysis.

It is extremely unlikely that an overdose of Vitamin C can arise from use of **ALPHA Magnesium** at the concentrations present.

See “UNDESIRABLE EFFECTS”

PHARMACOLOGICAL PROPERTIES

Category D: Complementary Medicine

Discipline: Health Supplement

Classification: 34.12 Multiple substance formulation

Pharmacodynamic properties

Magnesium plays an important role in the efficient functioning of the human body. Several biochemical processes are regulated by Magnesium including blood pressure, nerve transmission, neuromuscular conduction (including cardiac excitability) and vasomotor tone, muscular contraction and insulin metabolism. Deficiency can impact the nervous, cardiovascular, gastric or musculo-skeletal systems.

More than 99% of Magnesium in the body is intracellular. Of this around 60% is concentrated in the bones while 20% is found in the muscles and another 20% is in the soft tissues and the liver. Around 20% of serum Magnesium is bound to proteins. 60-70% of this is bound to albumin and the remainder is bound to any one of more than 3700 proteins that Magnesium may be bound to.

Magnesium is a cofactor for more than 300 enzymes. Several of these enzymes which rely on Magnesium are responsible for the mitochondrial conversion of ADP to ATP (adenosine

triphosphate) the metabolism of ATP and other processes providing cellular energy, such as oxidative phosphorylation and glycolysis.

Magnesium is also essential for the correct functioning of enzymes and biological processes that are responsible for nerve function, muscle contraction, blood glucose, control, gating of calcium channels and transmembrane ion flux.

Vitamin C

ascorbic acid is an essential water-soluble vitamin and antioxidant. Ascorbic acid and its metabolite dehydroascorbic acid form a reversible redox system which enables myriad biological processes by transferring electrons to enzymes. Ascorbic acid plays a key role in producing and maintaining collagen in healthy connective tissue through the production of hydroxyproline from proline. The main symptoms of Ascorbic acid deficiency (scurvy) such as the slow healing of wounds, bone disorders, vascular fragility, and disorders of dentine formation, are the result of impaired collagen formation.

Pharmacokinetic properties

Magnesium is absorbed primarily via passive, paracellular absorption in the ileum of the small intestine. The rate of absorption declines with age. Absorption is inversely proportional to the amount consumed and is therefore highest in persons with Hypomagnesemia and in persons consuming less than the NRV values of Magnesium in their daily diet.

The elimination half-life of Magnesium is between 41 and 181 days and the large majority is excreted renally.

Magnesium does not appear to be metabolised.

Ascorbic acid is absorbed primarily in the upper part of the small intestine via sodium-dependent active transport. Absorption is dependent upon the amount of ascorbic acid taken at one sitting, with the absorbed percentage decreasing with an increased intake. It is therefore advisable to take oral ascorbic acid in small doses spread throughout the day, rather than in one single, larger dose.

The physiological body pool of vitamin C is about 1500 mg. Plasma protein binding of ascorbic acid is approximately 24%.

Ascorbic acid is metabolised via dehydroascorbic acid partly (0.3%) to oxalic acid and other products. When ingested in excessive quantities, however, ascorbic acid is largely excreted in unchanged form in the urine and faeces.

The elimination half-life following an oral dose of 1 g is about 13 hours. Below an oral intake of about 3 g vitamin C per day, the main route of excretion is renal. With doses exceeding 3 g, increasing quantities are excreted unchanged in the faeces.

Preclinical safety data

No specific study with this product was done, but the properties of the active ingredients of **ALPHA Magnesium** are well known.

PHARMACEUTICAL PARTICULARS

List of excipients

- ☒ **Excipients:** Vanilla Flavour (25 mg), Raspberry Flavour (200 mg), Carmosine Colouring (E122) (2.5 mg), Ponceau Colouring (E124) (2,5 mg) and a proprietary effervescent blend (2987 mg).
- ☒ **The effervescent blend** contains sodium bicarbonate, citric acid, polyethylene glycol and Silicon Dioxide.

Incompatibilities

Not applicable

Shelf life

24 Months

Special precautions for storage

Store at or below 25 °C

Keep the tube tightly closed in order to protect from moisture

Use within 30 days of opening

Nature and contents of container

10 effervescent tablets in polypropylene tube closed by a PE stopper.

Box of one or three tubes containing 10 or 30 tablets.

Special precautions for disposal and other handling.

Not applicable

APPLICANT (CERTIFICATE OF REGISTRATION)

Alpha Pharm (Pty) Ltd

Alpha Pharm Head Office, Ground Floor, Block D, 66 Corporate Park, cnr Lenchen & Von Willich Avenue, Centurion.

Tel : 012-643-5840. Email: speak-to-us@alphapharm.co.a

www.alphapharm.co.a

This leaflet was created in

February 2021

REGISTRATION NUMBER

To be allocated