

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Magnesium Complex Tablets 30

2. COMPOSITION

Each tablet contains:

Ingredients:	Elemental	NRV% *
Magnesium (as Oxide)	250,0	100%

* South African Nutrient reference values for individuals 4 years and older

For full list of excipients, see section 6.a

3. PHARMACEUTICAL FORM

White, round or oval tablet.

4. CLINICAL PARTICULARS

(a) Therapeutic indication

Contributes to:

- normal energy - yielding metabolism
- normal functioning of the nervous system
- normal electrolyte balance
- a reduction of tiredness and fatigue
- the maintenance of normal muscle function
- normal protein synthesis
- normal psychological function
- maintenance of normal bones, teeth & tissue formation.

Has a role in the process of cell division

Helps to metabolise carbohydrates, fats and proteins

A factor in the maintenance of good health.

(b) Dosage and method of administration

Adults: Take 1 tablet per day with a glass of water after a meal.

Do not exceed the recommended dose.

Always consult your healthcare professional if you are taking any other medicine.

Only take the medication as indicated on the packet or container.

If you skip a dose, do not take a double dose.

Take at least two hours before or after taking other medication.

(c) Contraindications

Hypersensitivity to any of the ingredients or the excipients. Not for use in children under the age of 18 years.

(d) Special warnings and precautions for use

Magnesium is **LIKELY UNSAFE** when taken by mouth in higher doses.

- Alcoholism: Alcohol abuse increases the risk for magnesium deficiency.
- Bleeding disorders: Magnesium seem to slow blood clotting. In theory, taking magnesium might increase the risk of bleeding or bruising in people with bleeding disorders.
- Diabetes: Diabetes increases the risk for magnesium deficiency. Poorly controlled diabetes reduces how much magnesium the body absorbs. Heart block:
- High doses of magnesium (typically delivered by IV) should not be given to people with heart block. A condition called myasthenia gravis:
- Magnesium given intravenously (by IV) might worsen weakness and cause breathing difficulties in people with a condition called myasthenia gravis.
- Kidney problems, such as kidney failure: Kidneys that don't work well have trouble clearing magnesium from the body.
- Taking extra magnesium can cause magnesium to build up to dangerous levels.
- Don't take magnesium if you have kidney problems.

Any other supplementation consisting of vitamins and minerals should be taken into account when prescribing / suggesting **VITATECH MAGNESIUM COMPLEX**.

(e) Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **VITATECH MAGNESIUM COMPLEX**, however the below information gathered from the literature on the active ingredients should be taken into consideration:

VITATECH MAGNESIUM COMPLEX may interact with the following medicines. Caution is advised when used concurrently:

Antibiotics (Aminoglycoside antibiotics). Some antibiotics can affect the muscles. These antibiotics are called aminoglycosides. Magnesium can also affect the muscles. Taking these antibiotics and getting a magnesium shot might cause muscle problems. Some aminoglycoside antibiotics include amikacin (Amikin), gentamicin (Garamycin), kanamycin (Kantrex), streptomycin, tobramycin (Nebcin), and others.

Antibiotics (Tetracycline antibiotics). Magnesium can attach to tetracyclines in the stomach. This decreases the amount of tetracyclines that the body can absorb. Taking magnesium along with tetracyclines might decrease the effectiveness of tetracyclines. To avoid this interaction, take calcium 2 hours before or 4 hours after taking tetracyclines. Some tetracyclines include demeclocycline (Declomycin), minocycline (Minocin), and tetracycline (Achromycin).

Antibiotics (Quinolone antibiotics). Magnesium might decrease how much antibiotic the body absorbs. Taking magnesium along with some antibiotics might decrease the effectiveness of some antibiotics. To avoid this interaction, take these antibiotics at least 2 hours before, or 4 to 6 hours after, magnesium supplements. Some of these antibiotics that might interact with magnesium include ciprofloxacin (Cipro), enoxacin (Penetrex), norfloxacin (Chibroxin, Noroxin), sparfloxacin (Zagam), trovafloxacin (Trovan), and grepafloxacin (Raxar).

Bisphosphonates. Magnesium can decrease how much bisphosphate the body absorbs. Taking magnesium along with bisphosphates can decrease the effectiveness of bisphosphate. To avoid this interaction, take bisphosphonate at least two hours before magnesium or later in the day. Some bisphosphonates include alendronate (Fosamax), etidronate (Didronel), risedronate (Actonel), tiludronate (Skelid), and others.

Medications for high blood pressure (Calcium channel blockers). Magnesium might



decrease blood pressure. Taking magnesium with medication for high blood pressure might cause your blood pressure to go too low. Some medications for high blood pressure include nifedipine (Adalat, Procardia), verapamil (Calan, Isoptin, Verelan), diltiazem (Cardizem), isradipine (DynaCirc), felodipine (Plendil), amlodipine (Norvasc), and others.

Muscle relaxants. Magnesium seems to help relax muscles. Taking magnesium along with muscle relaxants can increase the risk of side effects of muscle relaxants. Some muscle relaxants include carisoprodol (Soma), pipecuronium (Arduan), orphenadrine (Banflex, Disipal), cyclobenzaprine, gallamine (Flaxedil), atracurium (Tracrium), pancuronium (Pavulon), succinylcholine (Anectine), and others.

Water pills (Potassium-sparing diuretics). Some "water pills" can increase magnesium levels in the body. Taking some "water pills" along with magnesium might cause too much magnesium to be in the body. Some "water pills" that increase magnesium in the body include amiloride (Midamor), spironolactone (Aldactone), and triamterene (Dyrenium).

(f) Pregnant or Breastfeeding

If you are pregnant or breastfeeding, before using VITATECH MAGNESIUM COMPLEX, please consult your health care provider

(g) Ability to drive and use machines

VITATECH MAGNESIUM COMPLEX should not affect the ability of individuals to drive or operate machinery.

(h) Side Effects

- Magnesium is **LIKELY SAFE** for most people when taken appropriately. Doses less than 350 mg daily are safe for most adults. In some people, magnesium might cause stomach upset, nausea, vomiting, diarrhea, and other side effects. When taken in very large amounts (greater than 350 mg daily), magnesium is **POSSIBLY UNSAFE**. Large doses might cause too much magnesium to build up in the body, causing serious side effects including an irregular heartbeat, low blood pressure, confusion, slowed breathing, coma, and death. Always consult your health care provider for advice.

(i) Overdose

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

(j) Effects when no further used

There should be no side effects or any withdrawal symptoms after you stop using VITATECH MAGNESIUM COMPLEX

(5) PHARMACOLOGICAL PROPERTIES

(a) PHARMACOLOGICAL CLASSIFICATION

34.12 Category D (Health Supplement) [S0]

(b) PHARMACOLOGICAL ACTION

- Essential nutrients are substances required by the body to perform its basic functions and must be obtained from our diet since the human body cannot produce them. They have one or more of three basic functions: to provide energy, contribute to body structure, and/or regulate chemical processes in the

body.

- They're essential for many body functions, including building strong bones and teeth, regulating your metabolism, and staying properly hydrated. These basic functions allow us to detect and respond to environmental surroundings, move, excrete wastes, breathe, grow, and reproduction.
- When essential nutrients are in short supply or is not able to be utilized properly, a specific deficiency syndrome may be the result.
- When the deficient nutrient is resupplied before irreversible damage occurs, the signs and symptoms are reversed. Deficiency of essential nutrients is noticeable in several symptoms that can be easily observed and includes, but are not limited to, for example: weakness, tiredness, decrease in energy which can also lead to the risk of developing illnesses and health problems.
- Magnesium is a mineral that is important for normal bone structure in the body. People get magnesium from their diet, but sometimes magnesium supplements are needed if magnesium levels are too low. Low magnesium levels in the body have been linked to diseases such as osteoporosis, high blood pressure, clogged arteries, hereditary heart disease, diabetes, and stroke.

(6) PHARMACEUTICAL PARTICULARS

(a) Other ingredients

Microcrystalline cellulose, di-calcium phosphate & magnesium stearate

(b) Shelf life

2 years

(c) Storage conditions

Store at or below 25 °C.

Protect from sunlight and moisture.

Keep out of reach of children

Store in original packaging

Do not store in a fridge

Always seal the container properly before storage

(d) Presentation and packaging

White with green lid packaged container with tamperproof induction seal

Clearly labelled with detailed information printed on the label.

Containing 30 tablets.

Nett content weight: 30 x 1 g = 30 g

(e) Disposal and handling

Wrap the contents and the container properly in put in a plastic bag.

Dispose the wrapped package in the normal household waste bag after being dissolved in water.

(7) NAME AND ADDRESS OF REGISTRATION HOLDER

Serfie Imports & Exports (PTY) Ltd

Cnr Parkin & Delson Street, North End, Gqeberha 6001

Tel no: +27 (0) 41 816 3100

Email: info@vitatechhealth.com

Website: www.vitatechhealth.com



(8) REGISTRATION NUMBER

To be allocated

(9) DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

July 2021

(10) COMPLEMENTARY MEDICINE

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.