The Real Thing Tri-Mag Capsules

Complementary Medicine. Health Supplement.

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

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

THE REAL THING TRI-MAG CAPSULES contains magnesium (bis)glycinate 287 mg, magnesium citrate 287 mg, magnesium malate 287 mg, vitamin D3 11,25 microgram (450 IU) per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING TRI- MAG CAPSULES contains:

	Per capsule	Per 2 capsules
Magnesium (bis)glycinate	287 mg	574 mg
Magnesium citrate	287 mg	574 mg
Magnesium malate	287 mg	574 mg
Providing combined elemental magnesium	120 mg	240 mg
Cholecalciferol (vitamin D3)	11,25 microgram (450 IU)	22,5 microgram (900 IU)

The inactive ingredients include magnesium stearate (vegetable origin) and vegetable (hypromellose) capsule shells. The capsules are sugar free.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING TRI-MAG CAPSULES is a clear, hard vegetable capsule shell, size 00, containing a white to off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING TRI-MAG CAPSULES is a health supplement that helps with –

- Magnesium combined with vitamin D contribute to the development and maintenance of bones and teeth;
- Magnesium and vitamin D are factors in the maintenance of good health;
- Magnesium helps to metabolise carbohydrates, fats and proteins;
- Magnesium contributes to tissue formation, and contributes to the maintenance of normal muscle function;
- Vitamin D helps in the absorption and use of calcium and phosphorous.
- Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults and children older than 9 years: Take 2 (two) capsules orally daily with a glass of water or consult your healthcare practitioner. Take with meals to reduce gastrointestinal effects.

Paediatric population

Dosage of greater than 100 mg magnesium per day is not suitable for use in children younger than 9 years.

4.3 Contraindications
Hypersensitivity to any of the ingredients.
Vitamin D is contraindicated if there is hypercalcemia.

4.4 Special warnings and precautions for use
Chronic alcohol use and diabetes increases the risk for magnesium deficiency. Kidney disease reduces magnesium excretion and increases the risk for hypermagnesemia; use cautiously.
Magnesium salts can cause a false increase in serum alkaline phosphatase test results, and a false increase in serum calcium test results in some procedures using EDTA. Use of proton pump inhibitors are linked to increased risk of hypomagnesaemia.
Doses of vitamin D higher than that recommended long term can lead to hypercalcaemia or hyperphosphataemia. Hypercalcaemia can contribute to arteriosclerosis, particularly in patients with kidney disease. Vitamin D should be used with caution in patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcaemia occurs. Plasma phosphate concentrations should be controlled during vitamin D therapy.

Vitamin D may increase calcium levels in patients with histoplasmosis, with increased risk of complications such as kidney stones and calcified tissue.
Vitamin D may increase calcium levels and lead to hypercalcaemia in patients with hyperparathyroidism, lymphoma, sarcoidosis and tuberculosis with increased risk of complications such as kidney stones and calcified tissue. Vitamin D may increase calcium levels and increase risk of arteriosclerosis in patients with renal failure.
Vitamin D may cause increased lab values of urinary and blood calcium, phosphate, albumin, blood urea nitrogen, serum cholesterol, aspartate aminotransferase and alanine aminotransferase, especially with high doses.

4.5 interactions with other medicines and other forms of interaction
Other medicines affecting THE REAL THING TRI-MAG CAPSULES:
Potassium-sparing diuretics and boron decrease excretion of magnesium, possibly increasing magnesium levels.
High doses of calcium can decrease dietary magnesium absorption. High doses of zinc may decrease magnesium absorption.
Aminoglycoside antibiotics and amphotericin B can cause nephrotoxicity which causes increased urinary loss of electrolytes such as magnesium.
Cetuximab, corticosteroids, digoxin, some diuretics, panitumumab and tacrolimus cause increased loss of magnesium in the urine. Cyclosporine and pentamidine may damage renal tubules and increase magnesium losses in the urine.
Oestrogens reduce serum levels of magnesium by increasing its uptake into body tissues.
Foscarnet can increase removal of magnesium from the body, causing symptomatic hypomagnesemia. Proton pump inhibitors can cause hypomagnesemia.
Penicillamine can reduce magnesium absorption by chelating magnesium in the gut.
High doses of sodium phosphates deplete magnesium.
Calcipotriene taken with vitamin D increases the risk of hypercalcaemia.
Orlistat decreases absorption and blood levels of vitamin D. Separate the dosing time by at least 2 hours.

THE REAL THING TRI-MAG CAPSULES affecting other medicines:
Magnesium can decrease the absorption of bisphosphonates and tetracyclines; separate doses by at least 2 hours.
Magnesium can form insoluble complexes with quinolones and decrease their absorption; advise patients to take quinolones at least 2 hours before, or 4-6 hours after magnesium.
Magnesium increases the systemic absorption of sulfonylureas, increasing their effects and side effects.

Vitamin D might increase the absorption of magnesium.
Vitamin D increases the absorption of calcium in some people. Hypercalcaemia induced by high-doses of vitamin D can reduce the therapeutic effects of verapamil for arrhythmia.
There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics, calcium or phosphate; plasma-calcium levels should be monitored.

4.6 Fertility, pregnancy and lactation
Advise the patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. When magnesium is used in pregnant women, foetal heart rate should be monitored and use within 2 hours of delivery should be avoided.
It is safe to take orally at the recommended dosage if pregnant or breastfeeding. Higher dosages are possibly unsafe.
No fertility data is available.

4.7 Effects on ability to drive and use machines
THE REAL THING TRI-MAG CAPSULES may have a minor influence on the ability to drive and use machines due to possible undesirable effects.

4.8 Undesirable effects
a. Summary of the safety profile
Gastrointestinal effects are the most commonly documented undesirable effects for these active ingredients.

b. List of adverse reactions
Blood and lymphatic disorders
Hypercalcaemia (rare), usually in patients with impaired renal function or in those taking vitamin D in excessive doses.
Hypermagnesaemia is uncommon, except in patients with renal impairment. Higher doses than recommended in children can cause symptomatic hypermagnesaemia including hypotension, nausea, vomiting and bradycardia.

Eye disorders
Visual impairment or nystagmus have been reported following magnesium supplementation (rare).

Gastrointestinal disorders
Gastrointestinal irritation (common), nausea (common), vomiting (common), diarrhoea (common), dry mouth. Higher doses than recommended in children can cause diarrhoea.

Skin and subcutaneous disorders
Hypersensitivity reactions.

Reproductive system and breast disorders
Vaginal discharge and itching (rare).
Frequencies of all adverse events are not known.

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. Healthcare 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
Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail adr@therealthing.co.za

4.9 Overdose
With an overdose, side effects can be precipitated and/or be of increased severity. Loose stools and diarrhoea may occur with large doses of magnesium. In children higher doses than recommended can cause diarrhoea and symptomatic hypermagnesemia including hypotension, nausea, vomiting and bradycardia.
Symptoms of magnesium toxicity include thirst, hypotension, central nervous system depression, lethargy, drowsiness, sedation, confusion, muscle weakness, skeletal muscle paralysis, loss of tendon reflexes, respiratory depression, cardiac arrhythmias, and in extreme cases coma, cardiac arrest and death. Renal insufficiency increases the likelihood of toxicity due to hypermagnesemia.

Excessive doses of vitamin D can lead to vitamin D intoxication with symptoms of hypertension (rare), pancreatitis, osteoporosis, decreased growth in children, calcific conjunctivitis and photophobia, psychosis (rare), runny nose, azotemia (rare), anaemia, weight loss, anorexia, metastatic calcification, generalized vascular calcification, hypercalcaemia with kidney stones or kidney insufficiency, seizures, increased risk of certain types of cancer. Symptoms of renal impairment include frequency, night time awakening to urinate, thirst, inability to concentrate urine, proteinuria and is usually reversible with discontinuing vitamin D supplements.
Vitamin D overdose can lead to hyperphosphatemia or hypercalcaemia. Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, and renal and cardiovascular damage. Symptoms of vitamin D overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence and vertigo.
In the event of overdose, advise the patient to stop taking the supplement. Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
THE REAL THING TRI-MAG CAPSULES belongs to category D Complementary Medicines, Health Supplements, class 34.12 Multiple Substance Formulation.
As a vitamin/ mineral supplement it contributes to the maintenance of overall good health.
THE REAL THING TRI-MAG CAPSULES consists of three forms of chelated magnesium – bisglycinate, citrate and malate.

Oral magnesium effectively treats hypomagnesemia. During magnesium deficiency bone resorption takes place which releases calcium and magnesium from bone. Magnesium is important for normal bone structure. Magnesium increases bone mineral density and decreases bone loss in postmenopausal patients, and in postmenopausal patients with osteoporosis.
It is suggested that adequate intakes of magnesium alone, or in combination with other minerals and vitamin D reduces bone turnover, and increases bone density.
Vitamin D is an essential fat-soluble vitamin. Vitamin D3 is metabolized in the body to its active metabolite, calcitriol.
Oral vitamin D prevents and treats vitamin D deficiency. The main function of vitamin D is to regulate serum calcium and phosphorus concentrations and bone mineralisation. Regular intake of oral vitamin D with calcium helps to prevent the progression of osteoporosis; it might also reduce the risk of fracture in some patients. Vitamin D facilitates the intestinal absorption of calcium. Calcium and vitamin D work synergistically in the prevention of bone loss and fractures.

5.2 Pharmacokinetic properties
Magnesium requires both parathyroid hormone and vitamin D for absorption. About one third of dietary magnesium is absorbed from the small intestine; the fraction absorbed increases as the body's magnesium store decreases. Body stores are divided between

skeleton and soft tissue. One third of skeletal magnesium acts as a reservoir to maintain extracellular magnesium concentrations. Magnesium is excreted primarily via the kidneys. [2(ss), 4(e)] Small amounts of magnesium are distributed in breast milk. Magnesium crosses the placenta.

Vitamin D substances are well absorbed from the gastrointestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption. Dietary vitamin D is transported primarily by chylomicron, which allows it to be distributed to peripheral tissues. Vitamin D can be stored in adipose tissue and muscle tissue for long periods of time. It is slowly released from such storage sites and from the skin where it is formed in the presence of sunlight or ultra-violet light. Vitamin D3 (cholecalciferol) is biologically inert. If not taken up by peripheral tissue, it is converted to calcitriol. It is hydroxylated in the liver and thereafter in the kidneys to its active form, calcitriol. Patients with chronic renal failure may require forms of vitamin D (such as calcitriol) that do not require hydroxylation.
Vitamin D and its metabolites are excreted mainly in the bile and faeces, with only small amounts appearing in the urine.

Paediatric population
No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
The inactive ingredients include:

- magnesium stearate (vegetable origin)
- vegetable (hypromellose) capsule shell

6.2 incompatibilities
Not applicable.

6.3 Shelf life
THE REAL THING TRI-MAG CAPSULES has a shelf life of 2 years when stored in a cool, dry place at or below 25 °C.

6.4 Special precautions for storage
Store in an airtight container, protected from light.

6.5 Nature and contents of container
THE REAL THING TRI-MAG CAPSULES is packed in a 200 ml amber glass bottle with a non-child resistant 45 mm polyethylene black or white screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 90 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

6.6 Special precautions for disposal
No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION
The REAL THING FOOD SUPPLEMENTS (PTY) LTD
9 Westlake Drive
Westlake 7945, Cape Town
Telephone: 021-701 0244
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8 REGISTRATION NUMBER
(To be allocated)

9 DATE OF FIRST AUTHORISATION
(To be allocated)

10 DATE OF REVISION OF TEXT
This is the first edition.

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