## The Real Thing Tri-Mag Capsules

**SCHEDULING STATUS:** S0

THE REAL THING TRI- MAG CAPSULES contain magnesium (bis)glycinate 287 mg, magnesium citrate 287 mg, magnesium malate 287 mg, vitamin D3 11,25 microgram (450 IU) per capsule. The capsules are sugar free.

Complementary Medicine. Health Supplement.

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

Read all of this leaflet carefully because it contains important information for you THE REAL THING TRI-MAG CAPSULES is available without a doctor's prescription, for you to maintain your health. Nevertheless you still need to use THE REAL THING TRI-MAG CAPSULES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share THE REAL THING TRI-MAG CAPSULES with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

#### What is in this leaflet

- 1. What THE REAL THING TRI-MAG CAPSULES is and what it is used for
- 2. What you need to know before you take THE REAL THING TRI-MAG CAPSULES
- 3. How to take THE REAL THING TRI-MAG CAPSULES
- Possible side effects
- 5. How to store THE REAL THING TRI-MAG CAPSULES
- 6. Contents of the pack and other information

## 1. What THE REAL THING TRI-MAG CAPSULES is and what it is used for

THE REAL THING TRI-MAG CAPSULES is a health supplement. It offers the following health benefits for adults and children older than 9 years -

THE REAL THING TRI-MAG CAPSULES is a specifically formulated, supplement containing magnesium and vitamin D, all playing an important role in the development and maintenance of bones and teeth. When sufficient vitamin D is combined with calcium intake, a healthy diet and regular exercise, it may reduce the risk of developing osteoporosis (weakening of bones).

As a health supplement it also -

- Contributes to the maintenance of good health;
- Helps to metabolise carbohydrates, fats and proteins;
- Contributes to the formation of body tissue and the maintenance of normal muscle function;
- Helps with the absorption of calcium and phosphorous by the body.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition, as well as mental and physical performance.

# 2. What you need to know before you take THE REAL THING TRI-MAG CAPSULES Do not take THE REAL THING TRI-MAG CAPSULES

- If you are allergic or hypersensitive to magnesium (bis)glycinate, magnesium citrate, magnesium malate, vitamin D3 or any of the other ingredients of THE REAL THING TRI-MAG CAPSULES (listed in section 6).
- If you have hypercalcaemia (abnormally high level of circulating calcium in the blood).

## Warnings and precautions

Take special care with THE REAL THING TRI-MAG CAPSULES:

- If you use alcohol long term.
- If you have diabetes.
- If you have reduced kidney function or kidney disease.
- If you have a medical condition associated with high levels of calcium.
- High doses of vitamin D over a long period of time can lead to hypercalcaemia (calcium levels in your blood are above normal) or hyperphosphataemia (phosphate levels in your blood are above normal).
- If you have heart disease.
- If you have histoplasmosis (an infection due to breathing in spores of a fungus).
- If you have hyperparathyroidism (high levels of parathyroid hormone in your blood).
- If you have lymphoma (a type of cancer).
- If you have sarcoidosis (small patches of red and swollen body tissue).
- If you have tuberculosis.
- If you take THE REAL THING TRI-MAG CAPSULES for long periods of time, ask your doctor to check your calcium, phosphate, albumin, blood urea nitrogen, serum cholesterol, aspartate aminotransferase and alanine aminotransferase levels.

#### Children and adolescents

THE REAL THING TRI-MAG CAPSULES is not suitable for use in children younger than 9 years.

## Other medicines and THE REAL THING TRI-MAG CAPSULES

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Other medicines may affect THE REAL THING TRI-MAG CAPSULES:

- Potassium-sparing diuretics and boron might increase your magnesium levels.
- High doses of calcium or zinc may decrease your magnesium levels.
- Aminoglycoside antibiotics and amphotericin B can cause reduced kidney function, which causes increased loss of electrolytes such as magnesium.
- Cetuximab, corticosteroids, digoxin, some diuretics, panitumumab, pentamidine, tacrolimus, cyclosporine and Foscarnet may cause increased loss of magnesium.
- Oestrogens reduce serum levels of magnesium by increasing its uptake into body tissues.
- Proton pump inhibitors can cause low blood levels of magnesium.
- Penicillamine can reduce absorption of magnesium.
- High doses of sodium phosphates deplete your magnesium
- Calcipotriene taken with vitamin D increases the risk of high calcium levels.
- Orlistat decreases the absorption and blood levels of vitamin D. Take these at least 2 hours apart.

#### THE REAL THING TRI-MAG CAPSULES may affect 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; take quinolones at least 2 hours before, or 4-6 hours after magnesium.
- Magnesium can increase the absorption of sulfonylureas, thereby increasing their effects and side effects.
- Vitamin D can increase magnesium absorption.
- Vitamin D increases the absorption of calcium in the small intestine. Hypercalcaemia induced by high-doses 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. Monitor your calcium intake.

## Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The dosage of THE REAL THING TRI-MAG CAPSULES requires control during pregnancy and breastfeeding, therefore use cautiously. Monitor foetal heart rate prior to delivery.

## Driving and using machines

THE REAL THING TRI-MAG CAPSULES may have a minor influence on these abilities. It is not always possible to predict to what extent THE REAL THING TRI-MAG CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which THE REAL THING TRI-MAG CAPSULES affects them.

#### 3. How to take THE REAL THING TRI-MAG CAPSULES

Do not share medicines prescribed for you with any other person.

Always take THE REAL THING TRI-MAG CAPSULES exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children 9 years and older is:

- Take 2 (two) capsules orally once a day with a glass of water, or consult your healthcare provider.
- Take with meals to reduce gastrointestinal effects.

Do not take more than the recommended dose, unless under direct supervision of your doctor.

## If you take more THE REAL THING TRI-MAG CAPSULES than you should

More severe side effects may occur if you have taken too much THE REAL THING TRI-MAG CAPSULES. If you are not feeling well, stop taking the supplement and consult your doctor. Treat the symptoms that may occur.

In the event of overdosage, stop taking the supplement and consult your doctor or pharmacist. If neither is available, seek help at your nearest hospital or poison centre. Take this information leaflet and product container with you for identification.

#### If you forget to take THE REAL THING TRI-MAG CAPSULES

Do not take a double dose to make up for the forgotten individual doses.

If you forget to take it for a day or two, just start again at the regular daily dose.

## If you stop taking THE REAL THING TRI-MAG CAPSULES

You may not achieve optimal benefits if you do not take it regularly.

#### 4. Possible side effects

THE REAL THING TRI-MAG CAPSULES can have side effects.

Not all side effects reported for it are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking THE REAL THING TRI-MAG CAPSULES, please consult your healthcare provider for advice.

If any of the following happens, stop taking THE REAL THING TRI-MAG CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital. Take this information leaflet with you.

Hypersensitivity reactions

These are all very serious side effects. If you have them, you may have had a serious reaction to THE REAL THING TRI-MAG CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- High calcium levels in the blood (less frequent)
- High magnesium levels in the blood, which in children can include low blood pressure, nausea, vomiting and slow heart rate
- Visual impairment or nystagmus (rapid, uncontrolled eye movements) (less frequent)
- Vaginal discharge and itching (less frequent)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

## Frequent side effects:

- Gastrointestinal irritation
- Nausea
- Vomiting
- Diarrhoea

#### Frequencies not known:

• Dry mouth

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <a href="https://www.sahpra.org.za/Publications/Index/8">https://www.sahpra.org.za/Publications/Index/8</a>. By reporting side effects, you can help provide more information on the safety of THE REAL THING BONE REVOLUTION CAPSULES.

Alternatively, side effects may be reported directly to The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or email <u>adr@therealthing.co.za</u>.

#### 5. How to store THE REAL THING TRI-MAG CAPSULES

Store all medicines out of the reach of children.

- Store in a cool, dry place at or below 25 °C.
- Store in an airtight container, protected from light.
- Keep the container tightly closed.
- Protect from heat and moisture.
- Do not store in the bathroom.
- Do not use after the expiry date stated on the label or container.

Do not use THE REAL THING TRI-MAG CAPSULES if you notice the capsules appear slimy or have discoloured from date of opening.

Return any unused or expired medicine to your pharmacist for proper disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information What THE REAL THING TRI-MAG CAPSULES contains

The active substances are:

	Per capsule	Per daily dose (2 capsules)
Magnesium (bis)glycinate*	287 mg	547 mg
Magnesium citrate*	287 mg	547 mg
Magnesium malate*	287 mg	547 mg
*Providing magnesium	120 mg	240 mg

22,5 microgram (900 IU)

\*Elemental quantities calculated.

• The other ingredients are magnesium stearate (vegetable origin) and vegetable (hypromellose) capsule shell.

What THE REAL THING TRI-MAG CAPSULES looks like and contents of the pack THE REAL THING TRI-MAG CAPSULES is a clear, hard vegetable capsule, size 00, containing a white to off-white coloured powder.

THE REAL THING TRI-MAG CAPSULES are packed in a 200 ml amber glass bottle with a non-child resistant 45 mm polyethylene black 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.

## **Holder of Certificate of Registration**

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD 9 Westlake Drive Westlake 7945, Cape Town Telephone: 021-701 0244

E-mail: info@therealthing.co.za

#### This leaflet was last revised in

This is the first edition.

## Registration number

(To be allocated)

## Access to the corresponding Professional Information

The Professional Information is located at: <a href="https://www.therealthing.co.za/index.php/the-range/bones-and-joints/13-the-real-thing/the-range/98-tri-mag">https://www.therealthing.co.za/index.php/the-range/bones-and-joints/13-the-real-thing/the-range/98-tri-mag</a>
Or obtain the Professional Information directly from THE REAL THING FOOD SUPPLEMENTS (PTY) LTD using the contact details listed under Holder of Certificate of Registration.

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