The Real Thing Bone Revolution Capsules

SCHEDULING STATUS: S0

THE REAL THING BONE REVOLUTION CAPSULES contains Aquamin F® (calcium and magnesium) 445 mg, magnesium citrate 235 mg, boron amino acid chelate 22 mg, zinc citrate 12 mg, selenium amino acid chelate 10 mg, manganese gluconate 8 mg, MenaQ7® 10 mg (vitamin K2 0,02 mg), vitamin D3 5 microgram (200 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 BONE REVOLUTION CAPSULES is available without a doctor's prescription, for you to maintain your health. Nevertheless you still need to use THE REAL THING BONE REVOLUTION 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 BONE REVOLUTION 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 BONE REVOLUTION CAPSULES is and what it is used for
2. What you need to know before you take THE REAL THING BONE REVOLUTION CAPSULES
3. How to take THE REAL THING BONE REVOLUTION CAPSULES
4. Possible side effects
5. How to store THE REAL THING BONE REVOLUTION CAPSULES
6. Contents of the pack and other information

1. What THE REAL THING BONE REVOLUTION CAPSULES is and what it is used for

THE REAL THING BONE REVOLUTION CAPSULES is a health supplement. It offers the following health benefits for adults -
THE REAL THING BONE REVOLUTION CAPSULES is a specifically formulated, bone-related supplement containing calcium and magnesium (Aquamin F®), with added vitamins and minerals that increase the intestinal absorption of calcium and phosphorous, all playing an important role in the development and maintenance of bones. When combined with a healthy diet and regular exercise, it may reduce the risk of developing osteoporosis (weakening of bones).
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 BONE REVOLUTION CAPSULES

Do not take THE REAL THING BONE REVOLUTION CAPSULES

- If you are allergic or hypersensitive to Aquamin F®, magnesium citrate, boron amino acid chelate, zinc citrate, selenium amino acid chelate, manganese gluconate, MenaQ7® (vitamin K2), vitamin D3 or any of the other ingredients of THE REAL THING BONE REVOLUTION CAPSULES (listed in section 6).
- If you have kidney stones.
- If you have hypercalcaemia (abnormally high level of circulating calcium in the blood).

Warnings and precautions
Take special care with THE REAL THING BONE REVOLUTION CAPSULES:

- If you have reduced kidney function or kidney disease.
- If you have a medical condition associated with high levels of calcium.
- If you have achlorhydria (no acid in your stomach fluid) you need to take THE REAL THING BONE REVOLUTION CAPSULES with a meal to increase the absorption of calcium.
- If you smoke, it may interfere with calcium absorption.
- If your diet is high in caffeine, sodium or protein, it may increase your urinary excretion of calcium.
- If you have iodine deficiency, THE REAL THING BONE REVOLUTION CAPSULES may worsen your hypothyroidism.
- It may cause excessive bleeding, which needs to be considered if you plan to have an operation within 2 weeks of taking these capsules.
- If you have chronic liver disease, it may lead to manganese accumulation and toxicity.
- If you have iron-deficiency anaemia, you might have increased manganese absorption.
- 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 BONE REVOLUTION 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 BONE REVOLUTION CAPSULES is not suitable for use in children.

Other medicines and THE REAL THING BONE REVOLUTION CAPSULES
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Other products may affect THE REAL THING BONE REVOLUTION CAPSULES:

- Thiazide diuretics or vitamin D can increase the level of calcium in your body.
- Loop diuretics, large doses of aluminium, carbamazepine, phenobarbital, phenytoin, mineral oil or corticosteroids might decrease the level of calcium in your body.
- Stimulant laxatives should be used short term only as they might decrease your calcium absorption.
- Calcium and tetracycline antibiotics reduce each other's absorption, therefore take tetracyclines at least 2 hours before or 4-6 hours after calcium supplements or calcium-containing foods.
- A low fat, high fibre (bran) diet might reduce the absorption of calcium.
- Potassium-sparing diuretics and boron might increase 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 and tacrolimus, cyclosporine, capecitabine and Foscarnet may cause increased loss of magnesium.
- Oestrogens reduce serum levels of magnesium by increasing its uptake into body tissues.

- Penicillamine can reduce absorption of magnesium.
- High doses of sodium phosphates deplete your magnesium.
- Deferoxamine, EDTA in propofol, and thiazide diuretics might decrease your zinc levels.
- Iron supplements, penicillamine, phosphorous-containing preparations and tetracyclines may reduce the absorption of zinc.
- Calcium and iron can decrease manganese absorption.
- Zinc can increase manganese absorption and plasma levels.
- Coenzyme Q10 has vitamin-K like activity and may have additive effects of blood clotting if you are on anticoagulants.
- Large doses of vitamin E might block the effects of vitamin K with resultant increased bleeding risk in people who are taking warfarin.
- 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 BONE REVOLUTION CAPSULES may affect other products:

- Calcium salts reduce the absorption of bisphosphonates, sotalol, tetracycline antibiotics, fluoroquinolone antibiotics and quinoline antibiotics; take medication at least 2 hours before or 4-6 hours after calcium supplements.
- Calcium reduces levels of dolutegravir, elvitegravir and levothyroxine; take medication at least 2 hours before or 4-6 hours after calcium supplements.
- Calcium supplementation may decrease the absorption of dietary iron, zinc and magnesium, therefore take calcium supplements at bedtime.
- Calcium enhances the effects of digitalis glycosides on the heart.
- Calcium salts reduce the absorption of fluoride, therefore doses should be separated by at least 3 hours.
- 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.
- Boron might increase levels of magnesium.
- Zinc at high levels might reduce the absorption of magnesium.
- Zinc can decrease the levels and clinical effects of penicillamine, quinolone antibiotics, tetracycline antibiotics and iron. Take at least 2 hours before, or 4-6 hours after zinc.
- Selenium may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet drugs, or other products that have antiplatelet activity.
- Vitamin K can antagonize and reverse the therapeutic effects of warfarin; large doses of vitamin K can reduce the anticoagulant effect of warfarin.
- Vitamin D in high doses can increase magnesium absorption.
- Vitamin D increases the absorption of calcium in the small intestine; excessive amounts of vitamin D might increase the risk of hypercalcaemia. 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.

THE REAL THING BONE REVOLUTION CAPSULES with food and drink

Take THE REAL THING BONE REVOLUTION CAPSULES after low-fibre foods. Avoid phytates (tubers, legumes, seeds, nuts and unprocessed whole grains such as whole wheat, oats or rice).

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 BONE REVOLUTION CAPSULES requires control during pregnancy and breastfeeding, therefore use cautiously.

Driving and using machines
THE REAL THING BONE REVOLUTION CAPSULES may have a minor influence on these abilities.
It is not always possible to predict to what extent THE REAL THING BONE REVOLUTION 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 BONE REVOLUTION CAPSULES affects them.

3. How to take THE REAL THING BONE REVOLUTION CAPSULES
Do not share medicines prescribed for you with any other person.
Always take THE REAL THING BONE REVOLUTION 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 18 years and older is:

- Take 3 (three) capsules orally once a day with a glass of water, or consult your health care provider.
- Take with meals to reduce gastrointestinal effects.

Do not take more than the recommended dose, unless under direct supervision of your doctor.
Avoid taking more than 1 300 mg calcium per day; consider all sources, dietary and supplementation (count approximately 300 mg calcium per day from non-dairy foods and 300 mg calcium per day per cup of milk).

If you take more THE REAL THING BONE REVOLUTION CAPSULES than you should
More severe side effects may occur if you have taken too much THE REAL THING BONE REVOLUTION 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 over dosage, 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 leaflet and the product container with you for identification. In the event of zinc over dosage give milk or alkali carbonates and activated charcoal; do not induce vomiting.

If you forget to take THE REAL THING BONE REVOLUTION CAPSULES
If you forget to take it for a day or two, just start again at the regular daily dose. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking THE REAL THING BONE REVOLUTION CAPSULES
You may not achieve optimal benefits if you do not take it regularly.

4. Possible side effects
THE REAL THING BONE REVOLUTION 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 BONE REVOLUTION CAPSULES, please consult your healthcare provider for advice.

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

- Hypersensitivity reactions
- Allergic skin rash (less frequent)
- Skin and skin appendage (hair, nails and glands) lesions

These are all very serious side effects. If you have them, you may have had a serious reaction to THE REAL THING BONE REVOLUTION 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
- Visual impairment or nystagmus (rapid, uncontrolled eye movements) (less frequent)
- Calciphylaxis (calcium collecting in blood vessels of fat and skin tissue) resulting in skin ulcers and skin 'death' (flaking off at a faster rate) (less frequent)
- Heart attack
- Rapid heartbeat when administered before giving birth to a baby
- Vaginal discharge and itching

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:

- Headache
- Burping
- Flatulence (gas)
- Nausea
- Vomiting
- Diarrhoea
- Metallic taste due to zinc

Frequencies not known:

- Gastrointestinal discomfort
- Gastrointestinal irritation
- Inflammation of stomach lining
- Abdominal cramping or pain
- Dyspepsia (indigestion)
- Heartburn
- Mouth irritation
- 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: https://www.sahpra.org.za/Publications/Index/8. 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 021-7010244 or email adr@therealthing.co.za.

5. How to store THE REAL THING BONE REVOLUTION 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 BONE REVOLUTION 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 BONE REVOLUTION CAPSULES contains

- The active substances are:

	Per capsule	**Per daily dose (3 capsules)**
Aquamin F® (*Lithothamnium calcareum*) [cytoskeleton]**	445 mg	1335 mg
*Providing calcium	141 mg	423 mg
*Providing magnesium	9,2 mg	27,6 mg
Magnesium citrate	235 mg	705 mg
*Providing magnesium	26,9 mg	80,7 mg
Boron amino acid chelate	22 mg	66 mg
*Providing boron	0,96 mg	2,88 mg
Zinc citrate	12 mg	36 mg
*Providing zinc	3,58 mg	10,74 mg
Selenium amino acid chelate	10 mg	30 mg
*Providing selenium	18,4 microgram	55 microgram
Manganese gluconate	8 mg	24 mg
*Providing manganese	0,77 mg	2,31 mg
MenaQ7® (Menaquinone)	10,00 mg	30,00 mg
*Providing Vitamin K2	20 microgram	60 microgram
Cholecalciferol (Vitamin D3)	2,4 mg	7,2 mg
*Providing Vitamin D	5 microgram (200 IU)	15 microgram (600 IU)

*Elemental quantities calculated.

** Aquamin F® consists of mineralised red algae of the species *Lithothamnium sp.*

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

What THE REAL THING BONE REVOLUTION CAPSULES looks like and contents of the pack

THE REAL THING BONE REVOLUTION CAPSULES is a clear, hard vegetable capsule (hypromellose), size 00, containing a fine cream coloured powder.

THE REAL THING BONE REVOLUTION CAPSULES are packed in a 200 ml amber glass bottle with a 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.

Holder of Certificate of Registration
THE REAL THING FOOD SUPPLEMENTS (PTY) LTD
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Registration number
(To be allocated)

Access to the corresponding Professional Information
The Professional Information is located at: https://www.therealthing.co.za/index.php/the-range/bones-and-joints/13-the-real-thing/the-range/107-bone-revolution-caps
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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