DENSIMAX™ Tablets

Complementary Medicine
Health Supplement
This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:
Not Scheduled

PROPRIETARY NAME (AND DOSAGE FORM):
DensiMAX™ Tablets

COMPOSITION:
Each **DensiMAX™** tablet contains:

ACTIVE INGREDIENT	QUANTITY	DAILY DOSAGE	RDA
Calcium (from Aquamin™*_Lithothamnium calcareum_)	450 mg	900 mg	90%
Magnesium (from Aquamin™*_Lithothamnium calcareum_)	31 mg	62 mg	19%
Vitamin D3 (Cholecalciferol)	240 IU	480 IU	80%
Trace minerals (from Aquamin™*_Lithothamnium calcareum_) 72 Trace mineral including Boron, Chloride, Iron, Phosphorus, Potassium, Selenium, Sodium, Zinc	444 mg	888 mg	

Inactive ingredients: gum acacia, sodium carboxy-methyl cellulose, magnesium stearate.
DensiMAX™ tablets are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:
D 22.2 Vitamins – Other.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Aquamin is a marine-sourced multi-mineral, which is derived from the cytoskeleton the red algae *Lithothamnion calcareum*. Over the course of the aquatic plant's life, minerals are accumulated from the seawater, and stored as carbonate salts in the plant. Aquamin™ has the ability to improve osteoblast bone cell mineralisation and promote early bone mineral build-up. By re-mineralizing the cells, the number of osteoblasts s increased. Osteoblasts are responsible for new bone formation. Aquamins' osteogenic (bone tissue formation) response is improved by the addition of Vitamin D3.

INDICATIONS:
DensiMAX™ is a multi-mineral supplement that supports healthy bones and teeth and is a factor in the maintenance of good health. Calcium intake, when combined with sufficient Vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.

CONTRA-INDICATIONS:
DensiMAX™ tablets are contra-indicated in patients with:
- A hypersensitivity to calcium, vitamin D or to one of the other ingredients in **DensiMAX™** tablets including seafood, seaweeds and specific trace minerals.
- Hyper-calcaemia and/or hyper-calciuria (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Hyper-phosphatemia and/or hypo-phosphataemia (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Achlorhydria (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Smoking (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECUATIONS**").

WARNINGS AND SPECIAL PRECAUTIONS:
DensiMAX™ tablets should be used with care in patients with hyper-calcaemia and/or hyper-calciuria (see "**CONTRA-INDICATIONS**"). **DensiMAX™** tablets should be used with care in conditions that could lead to increased calcium absorption and hypercalcaemia such as, hyper-parathyroidism, renal insufficiency, sarcoidosis, bone tumour and myeloma (see "**CONTRA-INDICATIONS**"). **DensiMAX™** tablets should be used with care in conditions that could lead to decreased renal calcium reabsorption and hyper-calciuria such as kidney stones, nephron-calcinosis and kidney failure (see "**CONTRA-INDICATIONS**").

DensiMAX™ tablets should be used cautiously in patients with hyper-phosphatemia and/or hypo-phosphatemia. These patients should have increased monitoring of their serum phosphate levels (see "**CONTRA-INDICATIONS**").

DensiMAX™ tablets should be used with care in patients with achlorhydria as these patients have lower calcium absorption in a fasting state compared to patients with normal gastric acid secretion. When calcium is taken with a meal, reduced gastric acidity does not significantly impair absorption. Patients with achlorhydria should therefore take calcium with a meal (see "**CONTRA-INDICATIONS**").

DensiMAX™ tablets should be used with care in patients that smoke. Cigarette smoking decreases intestinal calcium absorption (see "**CONTRA-INDICATIONS**").

DensiMAX™ tablets should be used with care in patients undergoing surgery. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "**CONTRA-INDICATIONS**").

When starting, or stopping treatment with magnesium containing products, including **DensiMAX™** tablets, patients taking warfarin (or other coumarin anti-coagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "**INTERACTIONS**").

The use of **DensiMAX™** tablets in children and adolescents under 18 years of age is not recommended due to lack of adequate data (see "**DOSAGE AND DIRECTIONS FOR USE**").

Effects on the ability to drive or use machinery:
No studies on the effect of **DensiMAX™** tablets on the ability to drive or operate machines have been performed. It is unlikely that **DensiMAX™** tablets will affect the ability to drive or operate machines.

INTERACTIONS:
The herbs in **DensiMAX™** tablets may interact with the following medicines:
- Calcipotriene (Vitamin D analogue): may cause increased calcium absorption.
- Diltiazem: calcium can decrease effectiveness.
- Lithium: long-term lithium use may cause hypercalcemia.
- Potassium sparing diuretics: may increase levels of magnesium.
- Skeletal muscle relaxants: magnesium may increase levels.

There is some evidence that taking calcium and vitamin D with the anti-retroviral (ARV) drug, raltegravir, possibly reduces its levels. Until more is known, use with caution when taking raltegravir along with repeated doses of calcium.

The use of thiazide diuretics with calcium, as in **DensiMAX™** tablets could increase the risk of hypercalcemia, metabolic alkalosis and renal failure. Patients taking thiazide diuretics should consult their healthcare practitioner about appropriate calcium doses and to have their serum calcium levels and/or parathyroid function monitored regularly. These diuretics include chlorothiazide, hydrochlorothiazide, indapamide, metolazone and chlorthalidone.

The use of antacids with magnesium, as in **DensiMAX™** tablets, may reduce the levels of magnesium. Patients taking antacids should consult their healthcare practitioner and may need to adjust their dose of magnesium.

Magnesium, as in **DensiMAX™** tablets, may enhance the blood glucose lowering effects of anti-diabetic medicines. Patients on anti-diabetic medicines should monitor their glucose levels closely when taking **DensiMAX™** tablets.

Magnesium, as in **DensiMAX™** tablets, may increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel, dalteparin, enoxaparin, heparin) when taken concomitantly. Patients taking anti-coagulants or anti-platelet medicines should have their INR levels monitored more frequently when taking **DensiMAX™** tablets (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Calcium and magnesium, as in **DensiMAX™** tablets, may decrease absorption of bisphosphonates, taken to prevent loss of bone mass, when taken concomitantly. Advise patients to take bisphosphonates 30 minutes before **DensiMAX™** tablets, but preferably at a different time of day. Some of these medications include alendronate, etidronate, ibandronate, risedronate and tiludronate (see "**DOSAGE AND DIRECTIONS FOR USE**").

Calcium carbonate, as in **DensiMAX™** tablets, may reduce the effectiveness of levothyroxine in patients with hypothyroid. Advise patients to take levothyroxine and calcium supplement at least 4 hours apart (see "**DOSAGE AND DIRECTIONS FOR USE**").

Advise patients to separate doses of the below medicines by at least 2 hours before, or 4-6 hours after **DensiMAX™** tablets (see "**DOSAGE AND DIRECTIONS FOR USE**").

There is evidence that taking calcium, as in **DensiMAX™** tablets, with integrase inhibitors, used to treat HIV, may reduce levels of the medication. These medications include dolutegravir and elvitegravir.

Calcium and magnesium, as in **DensiMAX™** tablets, may decrease the absorption of tetracycline and quinolone antibiotics. Tetracyclines include demeclocycline, doxyclycline and minocycline. Quinolones include, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, gatifloxacin, Gemifloxacin and others.

Calcium, as in **DensiMAX™** tablets, may decrease the absorption of sotalol.

Magnesium, as in **DensiMAX™** tablets, may decrease levels of gabapentin.

PREGNANCY AND LACTATION:
Use **DensiMAX™** tablets under supervision of a healthcare practitioner.

DOSAGE AND DIRECTIONS FOR USE:
The recommended daily dose should not be exceeded.

Adults (18 years and older):
Take 1 tablet twice daily with meals or as prescribed.

Children (under 18 years of age):
Not recommended for use (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Bisphosphonates must be taken 30 min prior or at a different time of the day. Levothyroxin must be taken at least 4 hours apart from **DensiMAX™** tablets. Integrase inhibitors, tetracycline and quinoline antibiotics, sotalol and gabapectin must be taken at least 2 hours before, or 4-6 hours after **DensiMAX™** tablets (see "**INTERACTIONS**").

SIDE-EFFECS:
The following side-effects may occur with the use of **DensiMAX™** tablets.

Endocrine disorders:
Frequency unknown: Hypercalcemia, Milk-alkali syndrome, hyper-magnesemia.

Vascular disorders:
Frequency unknown: Myocardial infarct, atherosclerosis.

Respiratory, thoracic and mediastinal disorders:
Frequency unknown: Respiratory depression

Gastrointestinal disorders:
Frequency unknown: Gastro-intestinal irritation, nausea, vomiting, diarrhoea, belching, flatulence and acid reflux.

Renal and urinary disorders:
Frequency unknown: Nephro-calcinosis and renal insufficiency.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
The following symptoms may be experienced in the event of an overdose:
Thirst, hypotension, drowsiness, confusion, loss of tendon reflexes, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.
Contact a poison control centre in area.

IDENTIFICATION:
23 mm oblong off-white tablet.

PRESENTATION:
60 Tablets packed in a 125ml amber glass bottle with a seal and mustard gold screw cap in a product box and package insert.

STORAGE INSTRUCTIONS:
Store at or below 25 ºC in a dry place.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Flora Force Heath Products (Pty) Ltd.
Unit 3 Regent Park

Bell Crescent
Westlake
Cape Town

DATE OF PUBLICATION:
To be allocated.

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