



PROFESSIONAL INFORMATION

Scheduling Status:

SO

1. Proprietary Name

Vitamin D

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
Vitamin D (as Vita-Algae D™) Providing elemental Vitamin D 15 ug	6 mg

2.2 Sugar Free

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical form

30 white capsules packed in a 300 ml cylindrical white container with a lid and packaged in a single carton.

4. Clinical Information

4.1 Indications for Use

Where a deficiency in the active ingredients may exist. It may contribute to the protection of cells from oxidative stress and aid immune health. Vitamin D is an essential vitamin that helps regulate Calcium and Phosphorus in the body. Contributes to normal cell division. Contributes to normal blood Calcium levels. Contributes to the development and maintenance of strong bones and teeth. Contributes to the maintenance of normal muscle function. Contributes to the normal function of the immune system. Has a role in the process of cell division. Calcium intake, when combined with sufficient Vitamin D, healthy diet, and regular exercise, may reduce the risk of developing osteoporosis. A factor in the maintenance of good health.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Take 1 capsule per day, with a meal.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

4.3 Contraindications

Not recommended for individuals who are hypersensitive to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Do not exceed the recommended daily dose. Take product two hours before taking any other medication.

Not recommended for individuals under the age of 18.



4.5 Interactions

Aluminium is found in most antacids. Vitamin D can increase how much aluminium the body absorbs. If taking digoxin, talk to your doctor before taking Vitamin D. If taking Diltiazem, Verapamil, Diuretics (Thiazide) and Atorvastatin talk to your doctor, Vitamin D might increase or decrease the effects of these medications.

4.6 Pregnancy and Lactation

No known effects on pregnancy and breastfeeding

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

4.9 No known side effects if taking the correct dosage.

5 Pharmacological Classification:

Category D: 34.11 Vitamins.

Complementary Medicine.

6 Pharmacokinetic Properties

Absorption: Cholecalciferol and ergocalciferol are well absorbed form of Vit D. Cholecalciferol is the most efficient in elevating the 25-hydroxyvitamin D serum levels, that is the best indicator in measuring Vit D levels. In adults that are healthy and live healthy the bioavailability of Vit D from supplements are equivalent to the bioavailability of fortified foods.

Distribution: Vit D is transported in two different ways. Vitamin D that is produced in the skin via the sun is transported on the Vit D binding protein (DBP). Dietary vit D is transported via chylomicron, that allows Vit D to be distributed to peripheral tissue. The excess Vit D that is not taken up by the peripheral tissue is converted to calcitriol in the liver.

Metabolism: both forms of Vit D are inert and require hydroxylation to the form of Calcitriol in the body. The hydroxylation first occurs in the liver and then in the kidneys to calcitriol.

Excretion: certain diseases such as Diabetes, HIV and cancer may clear Vit D more rapidly.

7 Pharmaceutical Information

7.1 List of Excipients

Milled rice flour, vegetarian capsules.

7.2 Incompatibilities

None

7.3 Shelf Life

24 months from date of manufacture

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

30 white size 0 capsules packed in a 300 ml cylindrical white container with a lid and packaged.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©

371 Angus Crescent

Northlands Business Park



FOODGROWN™©

Version 1.0

May 2023

North Riding

Gauteng

South Africa

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9. Registration Number

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Still to be allocated

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10. Date of first authorisation

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Still to be allocated

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11. Date of review

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New

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12. Reference: <https://naturalmedicines.therapeuticresearch.com/>

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APPLICANT DETAILS:

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371 Angus Crescent

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Northlands Business Park

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Gauteng

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South Africa

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+27(0)87 265 4789

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