

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

To be allocated

PROPRIETARY NAME AND DOSAGE FORM:

Vitamin D3 (tablets)

COMPOSITION (per tablet):

Ingredients	
Vitamin D3 (Cholecalciferol 25mcg)	1000IU
Additional Ingredients	
Stevia Extract, Natural Colour (Beta Carotene), Natural Tropical Flavour, Citric Acid, Stearic Acid, Advantol 300™	

This product is suitable for vegetarians. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION:

Category D (Complementary Medicine) – Health Supplement.
This medicine has not been evaluated by SAHPRA for its quality, safety and intended use.

PHARMACOLOGICAL ACTION

PHARMACOKINETICS:

Vitamin D3 chewable tablet consists of Vitamin D3 (Cholecalciferol) of which, extensive pharmacokinetic studies have not been conducted.

PHARMACODYNAMICS:

Vitamin D3 chewable tablet is a high dose, once a day, Vitamin D3 (Cholecalciferol) which provides an essential nutrient to support optimal structural and functional roles in the body.

Vitamin D3 plays a vital role for stimulating the uptake and absorption of calcium while supporting mental and emotional wellbeing. Vitamin D3 is obtained from sun exposure and may be deficient in individuals who spend long working hours indoors.

INDICATIONS:

Vitamin D3 provides a supplementation for individuals who have limited daily sun exposure, require support for the absorption and utilization of calcium or need to manage mental and emotional wellbeing.

CONTRAINDICATIONS:

Vitamin D3 should be avoided in individuals with hyperparathyroidism, sarcoidosis or hypercalcaemia. It should not be taken in individuals under the age of 3 years. Do not use if a known hypersensitivity or allergy exists towards any of the ingredients. If in doubt, consult your medical practitioner or healthcare professional.

WARNINGS AND SPECIAL PRECAUTIONS:

Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or healthcare professional for advice. Do not exceed the recommended daily dosage. Do not use after the expiry date.

INTERACTIONS:

If you are taking any chronic medication, do not use this product without consulting your medical practitioner or healthcare professional.

Calcium Level Modulating Medication: Vitamin D3 as found in **Vitamin D3 chewable tablet** may affect the absorption of calcium and may result in hypercalcaemia.

Cholesterol Lowering Medication: Vitamin D3 levels may increase when taken concomitantly with Cholesterol Lowering Medication.

PREGNANCY AND BREASTFEEDING:

Although regarded as safe, consult your healthcare professional before use in pregnancy and breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:

Always tell your healthcare professional if you are taking any other medicine.
Adults and children (over the age of 3 years): Take 1 tablet daily or as professionally advised.

SIDE EFFECTS:

Immune System Disorders:

Frequency unknown: Hypersensitivity reactions

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

Long term use of high doses of this product is not advised. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. Treatment is symptomatic and supportive.

IDENTIFICATION:

Yellow/beige small speckled chewable tablet.

PRESENTATION:

60 or 120 tablets in a white bottle with an induction seal and a plastic tamperproof lid placed inside a cardboard carton.

STORAGE INSTRUCTIONS:

Store below 30°C in a dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF APPLICANT:

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DATE OF REGISTRATION

To be confirmed

CATEGORY

Category D (Complementary Medicine) – Health Supplement.
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Good Health Products Pty Ltd

REFERENCES

1. South African Medical Association (2016) South African Medicine Formulary, Health and Medical Publishing Group, page 87
2. WebMD (n.d), Vitamin D, WebMD, viewed 06 April 2020, <<https://www.webmd.com/vitamins/ai/ingredientmono-929/vitamin-d>>