

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Vitamin D₃ Tablets 30

2. COMPOSITION

Each tablet contains:

Ingredient	Elemental	NRV% *
Vitamin D ₃ as cholecalciferol	25 mcg 1000 IU	167%

* South African Nutrient reference values for individuals 4 years and older

For full list of excipients, see section 6.a

3. PHARMACEUTICAL FORM

White, round or oval tablet.

4. CLINICAL PARTICULARS

(a) Therapeutic indication

Vitamin D₃ helps in the absorption and use of calcium & phosphorous. Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis. Contributes to normal cell division, blood calcium levels, the development and maintenance of strong bones and teeth, normal function of the muscles- and the immune system, Vitamin D₃ plays a vital role in the maintenance of good health.

(b) Dosage and method of administration

Adults: Take 1 tablet per day with a glass of water after a meal.

Do not exceed the recommended dose.

Always consult your healthcare professional if you are taking any other medicine.

Only take the medication as indicated on the packet or container.

If you skip a dose, do not take a double dose.

Take at least two hours before or after taking other medication.

(c) Contraindications

Hypersensitivity to any of the ingredients or the excipients. Not for use in children under the age of 18 years.

(d) Special warnings and precautions for use

- (1) Metabolic effects have included hypercalcemia,
- (2) Renal conditions, although very uncommon, like hypercalciuria,
- (3) Dermatologic effects like Pruritus, rash or urticaria, although very rare,
- (4) Any allergic reactions to Vitamin D₃ or high levels of Calcium or Vitamin D₃ in your body.
- (5) Any condition that makes it hard for your body to absorb nutrients from food (malabsorption) and
- (6) Diabetes or phenylketonuria

Any other supplementation consisting of vitamins and minerals should be taken into account when prescribing / suggesting **VITATECH VITAMIN D₃**.

(e) Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **VITATECH Vitamin D₃**, however the below information gathered from the literature on the active ingredients should be taken into consideration:

VITATECH VITAMIN D₃ may interact with the following medicines. Caution is advised when used concurrently:

Vitamin D: high levels of Vitamin D may cause (hypervitaminosis D),
With heart conditions and medication, may contribute to irregular heartbeat and a reduce response to calcium channel blockers with raised calcium levels.
Iron with high blood pressure or hypertension medication may contribute to hypercalcemia and milk-alkali syndrome if used with dairy products.
With other vitamin/nutritional supplements
If you have any heart conditions,
If you have kidney disease,
An electrolyte imbalance or
Can exacerbate arrhythmias, particularly in patients receiving cardiac glycosides.
Administer cautiously in patients with or predisposed to cardiac arrhythmias. Clinical monitoring is recommended.

Please note: *Vitamin D deficiency* refers to a low level of Vitamin D in your body.

Vitamin D insufficiency classically manifests as bone disease, either rickets or osteomalacia.

(f) Pregnant or Breastfeeding

If you are pregnant or breastfeeding, before using **VITATECH VITAMIN D₃**, please consult your health care provider

(g) Ability to drive and use machines

VITATECH VITAMIN D₃ should not affect the ability of individuals to drive or operate machinery.

(h) Side Effects

Signs of an allergic reaction like:

- rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Growth problems in a child (not recommended to give to a child without speaking to your health care professional first),
- Upset stomach or throwing up.
- Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any side-effects while taking this medicine, please consult your health care provider for advice.

(i) Overdose

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

(j) Effects when no further used

There should be no side effects or any withdrawal symptoms after you stop using **VITATECH VITAMIN D₃**

(5) PHARMACOLOGICAL PROPERTIES

(a) PHARMACOLOGICAL CLASSIFICATION

34.12 Category D (Health Supplement) [S0]

(b) PHARMACOLOGICAL ACTION

- Essential nutrients are substances required by the body to perform its basic functions and must be obtained from our diet since the human body cannot produce them. They have one or more of three basic functions: to provide energy, contribute to body structure, and/or regulate chemical processes in the body.
- They're essential for many body functions, including building strong bones and teeth, regulating your metabolism, and staying properly hydrated. These basic functions allow us to detect and respond to environmental surroundings, move, excrete wastes, breathe, grow, and reproduction.
- When essential nutrients are in short supply or is not able to be utilized properly, a specific deficiency syndrome may be the result.
- When the deficient nutrient is resupplied before irreversible damage occurs, the signs and symptoms are reversed. Deficiency of essential nutrients is noticeable in several symptoms that can be easily observed and includes, but are not limited to, for example: weakness, tiredness, decrease in energy which can also lead to the risk of developing illnesses and health problems.
- Calcium and Vitamin D contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.

(6) PHARMACEUTICAL PARTICULARS

(a) Other ingredients

Microcrystalline cellulose, di-calcium phosphate & magnesium stearate

(b) Shelf life

2 years

(c) Storage conditions

Store at or below 25 °C.

Protect from sunlight and moisture.

Keep out of reach of children

Store in original packaging

Do not store in a fridge

Always seal the container properly before storage

(d) Presentation and packaging

White with green lid packaged container with tamperproof induction seal

Clearly labelled with detailed information printed on the label.

Containing 30 tablets.

Nett content weight: 30 x 1 g = 30 g

(e) Disposal and handling

Wrap the contents and the container properly in put in a plastic bag.



Dispose the wrapped package in the normal household waste bag.

(7) NAME AND ADDRESS OF REGISTRATION HOLDER

Serfie Imports & Exports (PTY) Ltd
Cnr Parkin & Delson Street, North End, Gqeberha 6001
Tel no: +27 (0) 41 816 3100
Email: info@vitatechhealth.com
Website: www.vitatechhealth.com

(8) REGISTRATION NUMBER

To be allocated

(9) DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

July 2021

(10) COMPLEMENTARY MEDICINE

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.
This medicine is not intended to diagnose, treat, cure or prevent any disease.