

**PROPRIETARY NAME AND DOSAGE FORM:**

**VITAMIN D3 TABLETS (30)**

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

**SCHEDULING STATUS:** Unscheduled

**COMPOSITION:** Each tablet contains:

| Ingredients   | Elemental value | *NRV |
|---|-----------------|------|
| Vitamin D <sub>3</sub> (as Cholecalciferol)                                 | 1000 IU         | 167% |
| Calcium (as Carbonate)  | 130 mg          | 10%  |
| * South African Nutrient reference values for individuals 4 years and older |                 |      |

**Other Ingredients:** Microcrystalline cellulose, magnesium stearate, silicon dioxide & coating.

**PHARMACOLOGICAL CLASSIFICATION:**

34.12 Category D (Health Supplement) [S0]

**PHARMACOLOGICAL ACTION:** Health supplement.

**INDICATIONS:** Indicated as a supplement where poor dietary intake of the listed active ingredients exist.

**CONTRA-INDICATIONS:**

- Hypersensitivity to any of the ingredients.

**WARNINGS AND SPECIAL PRECAUTIONS:**

- Large doses may give rise to hypervitaminosis.

**INTERACTIONS:**

No known interactions with existing conditions at recommended dose.

Medicines that will interact with Vitamin D3 are:

- Anticonvulsants (e.g., phenytoin, carbamazepine): May reduce the effectiveness of Vitamin D<sub>3</sub>.
- Weight loss medications (Orlistat): May reduce Vitamin D<sub>3</sub> absorption.
- Corticosteroids: Long-term use may affect Vitamin D<sub>3</sub> metabolism.
- Certain weight loss surgeries: May interfere with Vitamin D<sub>3</sub> absorption.
- Calcium supplements: High doses of Vitamin D<sub>3</sub> may increase calcium absorption, potentially leading to hypercalcemia.

**DOSAGE AND DIRECTIONS FOR USE:**

The recommended usage is:

- Adults take 1 tablet daily with meals.

Do not exceed the recommended dose. This product should not be used as a substitute for a balanced diet.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

This supplement is generally safe, but should be used with caution in individuals with the following medical conditions:

- Hypercalcemia: Vitamin D3 may increase calcium levels in the blood, leading to potential complications.
- Kidney disorders: Patients with kidney problems should consult their healthcare provider before taking Vitamin D3.
- Hypersensitivity: Individuals with known hypersensitivity to cholecalciferol or any other ingredients should avoid using Vitamin D3 supplements.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

In case of an accidental overdose, discontinue use and seek medical professional assistance immediately. Treatment is symptomatic and supportive.

Symptoms overdose may include:

- nausea, vomiting, constipation, excessive thirst, frequent urination, weakness, and confusion.

**IDENTIFICATION:**

Light yellow round pressed tablet.

**PRESENTATION:**

Packaged as a printed box with tamperproof seal, labelled with clear, detailed information printed on the box.

Contents are 3 blister packs of 10 round tablets each, containing 30 tablets in total.

**STORAGE INSTRUCTIONS:**

Store in a cool, dry place below 25 °C. Do not leave container open.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

To be allocated.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Vitatech

Physical address: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, South Africa.

Tel: 041 816 3100

Email: [ask@vitatechhealth.com](mailto:ask@vitatechhealth.com)

Website: [www.vitatechhealth.com](http://www.vitatechhealth.com)

**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

July 2023

**vitatech® NAPPI CODE:**

**3001760001**

**Claim it from your medical aid.**

**HANDELSNAAM EN DOSERINGSVORM:**

**VITAMIN D3 TABLETTE (30)**

**VRYWARING:** Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnoseering, behandeling, genesing of voorkoming van enige siekte nie.

**SKEDULERINGSSTATUS:** Ongeskeduleerd

**SAMESTELLING:** Elke tablet bevat:

| Bestandele  | Elementeel waarde | *NRV |
|---|-------------------|------|
| Vitamiën D <sub>3</sub> (as Cholekalsiferol)                            | 1000 IU           | 167% |
| Kalsium (as Karbonaat)  | 130 mg            | 10%  |
| * Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer |                   |      |

**Ander bestanddele is:** Mikrokristallyn sellulose, magnesiumstearaat, silikoondioksied & omhulsel.

**FARMAKOLOGIESE KLASSEKASIE:**

34.12 Kategorie D (Gesondheidsaanvuller) [S0]

**FARMAKOLOGIESE WERKING:** Gesondheidsaanvuller

**INDIKASIES:** Aangedui as 'n aanvulling waar swak dieetinname van die genoemde aktiewe bestanddele voorkom.

**KONTRA-LNDIKASIES:**

- Hipersensitiwiteit vir enige van die bestandele.

**WAASKUWINGS EN SPESIALE VOORSORGMATREËLS:**

- Groot dosisse mag lei tot hypervitaminose.

**INTERAKSIES:**

Geen bekende interaksies teen die aanbevole dosis.

Medisyne wat met Vitamiën D<sub>3</sub> kan interaksie hê is:

- Antikonvulsante (bv. fenitoin, karbamasepine): Mag die effektiwiteit van Vitamiën D<sub>3</sub> verminder.
- Medikasie vir gewigsverlies (Orlistat): Mag Vitamiën D<sub>3</sub> absorpsie verminder.
- Kortikosteroïede: Langtermyngebruik kan Vitamiën D<sub>3</sub>-metabolisme beïnvloed.
- Sekere gewigsverlies-operasies: Mag Vitamiën D<sub>3</sub> absorpsie inmeng.
- Kalsiumaanvullings: Hoë dosisse van Vitamiën D<sub>3</sub> kan kalsiumabsorpsie verhoog, wat moontlik tot hiperkalsemie kan lei.

**DOSIS EN GEBRUIKSAANWYSINGS:**

Die aanbevole gebruik is:

- Volwassenes neem daaglik 1 tablet saam met etes.

Moenie die aanbevole dosis oorskry nie. Die produk moenie 'n gebalanseerde dieët vervang nie.

**MOONTLIKE NEWE-EFFEKTE EN SPESIALE VOORBERGING:**

Hierdie aanvulling is oor die algemeen veilig, maar moet met sorg gebruik word by individue met die volgende mediese toestande:

- Hiperkalsemie: Vitamiën D3 kan kalsiumvlakke in die bloed verhoog, wat moontlike komplikasies kan veroorsaak.
- Nierversteurings: Pasiënte met nierprobleme moet hul gesondheidsorgverskaffer raadpleeg voordat hulle Vitamiën D3 neem.

- Hipersensitiwiteit: Individue met bekende hipersensitiwiteit vir cholekalsiferol of enige ander bestanddele moet die gebruik van Vitamiën D3-aanvullings vermy.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN**

In geval van 'n toevallige oordosis, staak die gebruik en soek onmiddellik mediese hulp. Behandeling is simptome en ondersteunend.

Simptome van 'n oordosis kan insluit:

- naarheid, braking, hardlywigheid, buitensporige dors, gereelde urinering, swakheid en verwardheid.

**IDENTIFIKASIE:**

Liggeel ronde gedrukte tablet.

**AANBIEDING:**

Verpak as 'n gedrukte boks met 'n verseëelde sertifikaat, gemerk met duidelike, gedetailleerde inligting wat op die boks gedruk is. Die inhoud bestaan uit 3 blaaspakke met 10 ronde tablette. Bevat 30 tablette.

**BERGINGSAAANWYSINGS:**

Bêre op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat. HOU BUIE BEREIK VAN KINDERS

**REGISTRASIE NOMMER:**

Word ge-allockeer.

**NAAM EN BESIGHEIDS ADRES VAN DIE APPLIKANT:**

Vitatech

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**DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING**

**PAMFLET:**  
Julie 2023

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