

PROPRIETARY NAME AND DOSAGE FORM:

**VITAMIN D3
ADULT GUMMIES (60)**

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 gummy contains:

Ingredients	Elemental value	*NRV
Vitamin D3 (as Cholecalciferol)	1000 iu	167%
* South African Nutrient reference values for individuals 4 years and older		

Other Ingredients: Glucose syrup, sucrose, purified water, gelatine (bovine), citric acid, flavourant, sodium citrate, colourant. Contains no artificial sweetener. Contains sugar: glucose (1 g), sugar (0.75g)
Gelatine is Halal certified at source.

PHARMACOLOGICAL CLASSIFICATION:

34. 13 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 digestive discomfort.

INTERACTIONS:

No known interactions with existing conditions at recommended dose.

Medicines that might interact with these gummies are:

- Anticonvulsants (e.g., phenytoin, carbamazepine): May reduce the effectiveness of Vitamin D₃.
- Weight loss medications (Orlistat): May reduce Vitamin D₃ absorption.
- Corticosteroids: Long-term use may affect Vitamin D₃ metabolism.
- Certain weight loss surgeries: May interfere with Vitamin D₃ absorption.
- Calcium supplements: High doses of Vitamin D₃ may increase calcium absorption, potentially leading to hypercalcemia.

DOSAGE AND DIRECTIONS FOR USE:

The recommended usage is:

Adults: Take 1 gummy daily

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 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:

Yellow, dome shaped gummy with a pineapple flavour.

PRESENTATION:

Clear jar with green lid, packaged with tamperproof induction seal, labelled with clear, detailed information printed on the label. Containing 60 gummies.

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

Website: www.vitatechhealth.com

DATE OF PUBLICATION OF THE PACKAGE INSERT:

July 2023

HANDELSNAAM EN DOSERINGSVORM:

**VITAMIN D3
ADULT GUMMIES (60)**

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 diagnosering, behandeling, genesing of voorkoming van enige siekte nie.
SKEDULERINGSTATUS: Ongeskeduleerd

SAMESTELLING: Elke gummy bevat:

Bestanddele	Elementeel waarde	*NRV %
Vitamiën D3 (as Cholekalsiferol)	1000iu	167
* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer		

Ander bestanddele is: Glukosestroop, suikrose, gesuiwerde water, gelatien (bees), sitroensuur, geur, natriumsitraat, kleurstof. Bevat geen kunsmatige versoeter. Bevat suiker: glukose (1g), suiker (0.75g)
Gelatien is Halal gesertifiseer by die bron.

FARMAKOLOGIESE KLASSEFIKASIE:

34.13 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 maag ongemak.

INTERAKSIES:

Geen bekende interaksies teen die aanbevole dosis.

Medisyne wat kan interaksie hê met die gummies is:

- Antikonvulsante (bv. fenitoin, karbamasepien): Mag die effektiwiteit van Vitamiën D₃ verminder.
- Medikasie vir gewigsverlies (Orlistat): Mag Vitamiën D₃ absorpsie verminder.
- Kortikosteroïede: Langtermyngebruik kan Vitamiën D₃-metabolisme beïnvloed.
- Sekere gewigsverlies-operasies: Mag Vitamiën D₃ absorpsie inmeng.
- Kalsiumaanvullings: Hoë dosisse van Vitamiën D₃ kan kalsiumabsorpsie verhoog, wat moontlik tot hiperkalsemie kan lei.

DOSIS EN GEBRUIKSAANWYSINGS:

Die aanbevole gebruik is:

Volwassenes: Neem 1 gummy daaglik.

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

MOONTLIKE NEWE-EFFEKTE EN SPESIALE VOORBERGING:

Hierdie aanvulling moet met versigtigheid gebruik word by individue met die volgende mediese toestande:

- Hiperkalsemie: Vitamiën D3 kan kalsiumvlakke in die bloed verhoog, wat moontlike komplikasies kan veroorsaak.

- Nierverstuurings: 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, swaakheid en verwardheid.

IDENTIFIKASIE:

Geel, koepelvormige gummy met 'n pynappel geur.

AANBIEDING: Deurskynende bottle met groen deksel, en 'n peuterbestande induksie-seël. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 60 gummies.

BERGINGSAAANWYSINGS:

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

REGISTRASIE NOMMER:

Word ge-allokeer.

NAAM EN BESIGHEIDS ADRES VAN DIE APPLIKANT:
Vitatech

Adress: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, Suid Afrika.

Tel: 041 816 3100

E-pos: ask@vitatechhealth.com

Webwerf: www.vitatechhealth.com

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET:

Julie 2023

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**VITAMIN D3
ADULT GUMMIES (60)**

DISCLAIMER: This medicine has not been evaluated by SAPHRA. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

Read all this leaflet carefully because it contains important information for you. This medicine is available without a doctor's prescription, for you to use as a vitamin supplement. Nevertheless, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must go see a doctor if you experience worrying symptoms.

SCHEDULING STATUS: Unscheduled

COMPOSITION: Each gummy contains:

Ingredients	Elemental value	*NRV
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* South African Nutrient reference values for individuals 4 years and older		

Other Ingredients: Glucose syrup, sucrose, purified water, gelatine (bovine), citric acid, flavourant, sodium citrate, colourant. Contains no artificial sweetener. Contains sugar: glucose (1 g), sugar (0.75g) **Gelatine is Halal certified at source.**

WHAT IS THIS SUPPLEMENT USED FOR:

- Vitamin D₃ (Cholecalciferol) offers several benefits, including:
- Immunity: Supports a healthy immune system.
 - Healthy Bones & Teeth: Promotes calcium absorption, vital for strong bones and teeth.
 - Calcium Absorption: Enhances the absorption of calcium from the diet.
 - Muscle Function: Supports proper muscle function.
 - Mood Regulation: May play a role in mood regulation and overall well-being.
 - Vitamin D₃ is essential for overall health, with a range of functions that contribute to vitality and well-being.

BEFORE YOU TAKE THIS SUPPLEMENT:

Do not take if you are allergic to any of the ingredients.

Take special care when taking any supplement:

- Do not exceed the daily recommended amount.
- Seek professional advice if suffering from any allergies.
- Seek professional advice if any other medications are being taken or another medical condition is present.
- If you are taking other supplements, read the label as these supplements may contain the same ingredients.
- If you are pregnant or breast feeding your baby, please consult your health care provider for advice before taking this medicine.
- These gummies contain sugar and are therefore not recommended for diabetics.

TAKING/USING OTHER MEDICATION:

There are no known interactions at the recommended dosage for healthy individuals. See "PACKAGE INSERT Interactions."

HOW TO TAKE:

The recommended usage is:

Adults: Take 1 gummy daily

IF YOU TAKE MORE THAN YOU SHOULD:

In the event of an overdose, consult your doctor or pharmacist immediately. If neither is available, contact that nearest hospital or medical centre. Treatment is symptomatic and supportive.

POSSIBLE SIDE EFFECTS:

- These supplements are generally well-tolerated when taken as directed. Symptoms of overdose may include:
- nausea, vomiting, constipation, excessive thirst, frequent urination, weakness, and confusion.

IDENTIFICATION:

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PRESENTATION:

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VRYWARING: Hierdie medisyne is nie deur SAPHRA geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie.

Lees alle inligting in die inligtingsblad noukeurig, dit bevat belangrike inligting vir die verbruiker. Die medisyne is beskikbaar sonder 'n dokters voorskrif, vir gebruik as 'n vitamien aanvulling. Nieteenstaande, dit is belangrik dat die produk korrek gebruik moet word om die beste resultate te verkry.

- Moenie die pamflet weggooi nie, dit mag dalk nodig wees om dit weer te lees
- Vra jou apteker indien jy meer inligting of advies nodig het
- Besoek die dokter indien daar kommerwekkende simptome is.

SKEDULERINGSSTATUS: Ongeskeduleerd

SAMESTELLING: Elke gummy bevat:

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WAARVOOR WORD HIERDIE AANVULLING GEBRUIK:

Vitamien D₃ (Cholekalsiferol) bied verskeie voordele, insluitend:

- Immuniteit: Ondersteun 'n gesonde immuunstelsel.
- Gesonde Bene & Tande: Bevorder kalsiumabsorpsie, wat noodsaaklik is vir sterk bene en tande.
- Kalsium Absorpsie: Verbeter die absorpsie van kalsium uit die dieet.
- Spierfunksie: Ondersteun behoorlike spierfunksie.
- Mood Regulering: Mag 'n rol speel in humeur regulering en algemene welstand.
- Vitamien D₃ is essensieel vir algemene gesondheid, met 'n verskeidenheid funksies wat bydra tot lewenskrag en welstand.

VOORDAT JY HIERDIE AANVULLING NEEM:

Moenie neem indien jy allergies is vir enige van die bestanddele.

Neem spesiale sorg wanneer jy enige aanvulling neem:

- Oorskry nie die daaglikse aanbevole hoeveelheid nie.
- Raadpleeg 'n professionele persoon as jy aan allergieë ly.
- Soek professionele advies as enige ander medikasie geneem word of as daar 'n ander mediese toestand aanwesig is.
- As jy ander aanvullings neem, lees die etiket aangesien hierdie aanvullings dieselfde bestanddele mag bevat.
- As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

- Hierdie gummies bevat suiker en word daarom nie aanbeveel vir diabeete nie

INTERAKSIES MET ANDER MEDISYNE:

Daar is geen bekende interaksies by die aanbevole dosis vir gesonde individue nie. Verwys na die «VOUBILJET interaksies»

HOE OM DIT TE GEBRUIK:

Die aanbevole gebruik is:

Volwassenes: Neem 1 gummy daaglik.

AS JY MEER NEEM AS WAT JY MOET:

In geval van 'n oordosis, raadpleeg onmiddellik jou dokter of apteker. As hulle nie beskikbaar is nie, kontak die naaste hospitaal of mediese sentrum. Behandeling is simptome en ondersteunend.

MOONTLIKE NEWE-EFFEKTE:

Hierdie aanvullings word gewoonlik goed verdra as dit soos voorgeskryf geneem word. Simptome van 'n oordosis kan insluit:

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

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