

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.11 Vitamins

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

D3 LIQUID, 20 ml

COMPOSITION

Each one (1) tablet of D3 LIQUID contains the following actives:

Vitamin D (as cholecalciferol) 25 µg (1000 I.U.)

Inactive Ingredients: : Ascorbic acid (antioxidant), medium-chain triglycerides, peppermint oil, rosemary (antioxidant), spearmint oil.

This product is gluten free. (Sugar free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

D3 LIQUID is important for immune function and contributes to the development and maintenance of strong bones and teeth.

Ingredients	Uses for ingredient
Vitamin D (as cholecalciferol)	Cholecalciferol (vitamin D3) is in a class of medications called vitamin D analogues. Cholecalciferol is needed by the body for healthy bones, muscles, nerves, and to support the immune system. It works by helping the body to use more of the calcium found in foods or supplements.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take D3 LIQUID if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

Laboratory tests: This medication may interfere with certain lab tests (such as blood tests for cholesterol), possibly causing false test results. Make sure lab personnel and all your doctors know you use this medicine.

WARNING AND SPECIAL PRECAUTIONS

Caution: Consult your healthcare practitioner before use.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : heart disease, diabetes, phenylketonuria (PKU), kidney disease or an electrolyte imbalance. If you are taking the following medication, please consult with your healthcare professional before taking: oral diabetes medicine, medicines that reduce stomach acid. : burosumab, phosphate binders. If any of the following happens, stop using D3 LIQUID and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;



These are all very serious effects. If you have them, you may have had a serious reaction to D3 LIQUID. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, constipation, loss of appetite, increased thirst, increased urination, mental/mood changes, unusual tiredness.

These are all very serious effects. If you have them, you may have had a serious reaction to D3 LIQUID. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults and children older than 1 years old: Take one (1) drop daily or as advised by your healthcare practitioner.

Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use D3 LIQUID if you notice visible signs of deterioration.

IDENTIFICATION

Clear to Light Yellow Liquid.

PRESENTATION

Presented in a 20ml glass amber bottle with a tamper resistant dropper cap.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

This medicine has not been evaluated by SAHPRA for quality, safety, or intended use.

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESSIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.11 Vitamie

HANDELSNAAM EN DOSEERVORM,

D3 LIQUID, 20 ml

SAMESTELING

Elke (1) tablet D3 LIQUID bevat die volgende aktiewe stowwe:

Vitamiën D3 (as cholekalsiferol) 25 µg (1000 I.E.)

Onaktiewe bestanddele: Askorbiensuur (antioksidant), mediumketting trigliseriede, pepermentolie, roosmaryn (antioksidant), spearmint olie. Hierdie produk is glutenvry (Suikervry)

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

D3 LIQUID is belangrik vir immuunfunksie en dra by tot die ontwikkeling en instandhouding van sterk bene en tande.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **D3 LIQUID** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlus, verhoogde dors, verhoogde urinering, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **D3 LIQUID** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind.

Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIE

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassenes en kinders ouer as 1 jaar oud: Neem daaglik een (1) druppel of soos aanbeveel deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerms teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **D3 LIQUID** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Helder tot liggeel vloeistof.

AANBIEDING

Aangebied in 'n 20 ml glas amber bottel met 'n peutebestande druppel.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur: Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension,
Sandton, 2146,
Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

Bestanddele	Gebruike vir bestanddeel
Vitamiën D3 (as cholekalsiferol)	Cholecalciferol (vitamiën D3) is in 'n klas medisyne wat vitamiën D-analoë genoem word. Cholecalciferol word deur die liggaam benodig vir gesonde bene, spiere, senuwees en om die immuunstelsel te ondersteun. Dit werk deur die liggaam te help om meer van die kalsium wat in voedsel of aanvullings voorkom, te gebruik.

KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **D3 LIQUID** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. **Laboratoriumtoets:** Hierdie medisyne kan inmeng met sekere laboratoriumtoets (soos bloedtoets vir kolesterool), wat moontlik vals toetsresultate kan veroorsaak. Maak seker dat laboratoriumpersoneel en al jou dokters weet dat jy hierdie aanvulling gebruik.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Let op: Raadpleeg jou gesondheidsorgpraktisyn voor gebruik.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: hartsiektes, diabetes, fenielketonurie (PKU), niersiekte of 'n elektrolietwanbalans. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: burosumab, fosfaatbindmiddels. As enige van die volgende gebeur, hou op om **D3 LIQUID** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling.