

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.11 Vitamins



### PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL

FORM - **D3 1000™, 30, 60 & 120 Tablets**

#### COMPOSITION

Each one (1) tablet of **D3 1000™** contains the following actives:

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

**Inactive Ingredients:** : Lime juice powder (*Citrus aurantifolia*), hydroxypropyl cellulose, lime flavour, citric acid, magnesium stearate, silicon dioxide

**Contains sweeteners:** Mannitol, steviol glycosides, xylitol

**This product is suitable for non-GMO, gluten free.**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**D3 1000™** features high potency vitamin D3— the most bioactive form of supplemental vitamin D. Vitamin D is important for maintaining healthy bone strength and immune function.

#### IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF **D3 1000™**

Contains Mannitol, steviol glycosides, xylitol which may have an effect on the glycaemic control of patients with diabetes mellitus and may have a laxative effect

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 1000™** 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

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 talking: oral diabetes medicine, medicines that reduce stomach acid. : bursosumab, phosphate binders. If any of the following happens, stop using **D3 1000™** 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 1000™**. 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 1000™**. 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:** Chew or swallow one (1) tablet daily with food or as directed 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 1000™** if you notice visible signs of deterioration.

#### IDENTIFICATION

Uncoated, round tablet.

#### PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### 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.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.11 Vitamiene

HANDELSNAAM EN DOSEERVORM,

## D3 1000™, 30, 60 & 120 tablette

SAMESTELING

Elke (1) tablet D3 1000™ bevat die volgende aktiewe stowwe:

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

**Onaktiewe bestanddele:** Lemmetjiesap poeier (Citrus aurantifolia), hidrokispropylselulose, lemmetjie geur, sitroensuur, magnesium stearaat, silikondioksied

**Bevat versoeters:** Mannitol, steviolglikosiede, xylitol

**Hierdie produk is geskik vir nie-GMO, glutenvry**

### FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**D3 1000™** bevat 'n hoësterkte vitamien D3, die mees bioaktiewe vorm van vitamien D. Vitamiene D is belangrik vir die instandhouding van gesonde beensterkte en immuunfunksie.

### BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN D3 1000™

Bevat Mannitol, steviolglikosiede, xylitol wat 'n effek kan hê op die glukemiese beheer van pasiënte met diabetes mellitus en 'n lakseermiddel kan hê.

Bestanddele	Gebruike vir bestanddeel
Vitamiene D3 (as cholekalsiferol)	Cholekalsiferol (vitamiene D3) is in 'n klas medisyne wat vitamien D-analoë genoem word. Cholekalsiferol 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-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **D3 1000™** 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 laboratoriumtoetses (soos bloedtoetses vir cholesterol), wat moontlik vals toetsresultate kan veroorsaak. Maak seker dat laboratoriumpersoneel en al jou dokters weet dat jy hierdie aanvulling gebruik.

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

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: bursosumab, fosfaatbindmiddels. As enige van die volgende gebeur, hou op om **D3 1000™** 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;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **D3 1000™** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-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 1000™** 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.

### INTERAKSIES

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**)

### DOSES EN AANWYSINGS VIR GEBRUIK

**Volwasse:** Kou of sluk daaglik een (1) tablet saam met kos of soos voorgeskryf 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.

Beskermt 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 1000™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Onbedekte, ronde tablet.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpseël, spons en silikagelsakke.

### 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 BESIGHEIDSAADRES 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.