

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.11 Vitamins

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### D3 1000™, 30, 60 & 120 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU

- **D3 1000™** is available without a doctor's prescription.
- Nevertheless, you still need to use **D3 1000™** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **D3 1000™** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **D3 1000™** is and what it is used for.
- What you need to know before you take **D3 1000™**.
- How to take **D3 1000™**.
- Possible side effects.
- How to store **D3 1000™**.
- Contents of the pack and other information.

#### WHAT D3 1000™ CONTAINS

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.**

#### WHAT D3 1000™ IS AND WHAT IT IS USED FOR

**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™

**D3 1000™** contains Mannitol, steviol glycosides, xylitol which may have an effect on the control of your blood sugar if you have diabetes mellitus, and may have a laxative effect.

#### BEFORE YOU TAKE D3 1000™

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

#### PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **D3 1000™** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **D3 1000™** may affect you.

#### TAKING OTHER MEDICINES WITH D3 1000™

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner

#### HOW TO TAKE D3 1000™

Do not share medicines prescribed for you with any other person. Always take **D3 1000™** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### 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.**

#### IF YOU TAKE MORE D3 1000™ THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.



#### IF YOU FORGET TO TAKE D3 1000™

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**D3 1000™** may have side effects.

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 practitioner before taking: burosumab, 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.

Not all side effects and interactions reported for **D3 1000™** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **D3 1000™**.

#### STORAGE AND DISPOSING OF D3 1000™

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **D3 1000™** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF D3 1000™

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

#### IDENTIFICATION OF D3 1000™

Uncoated, round tablet

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

19 November 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,

Sandton, 2146

Tel: 011-802-8101



## PASIENT INLIGTINGSBLAD

### SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.11 Vitamiene

HANDELSNAAM EN DOSEERVORM,

## D3 1000™, 30, 60 en 120 tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

### BELANGRIKE INLIGTING VIR U

- D3 1000™ is beskikbaar sonder doktersvoorskrif.
- U moet steeds D3 1000™ versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie D3 1000™ met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat D3 1000™ is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy D3 1000™ neem.
- Hoe om D3 1000™ te neem.
- Moontlike newe-effekte.
- Hoe om D3 1000™ te bêre.
- Inhoud van die pak en ander inligting

### WAT D3 1000™ BEVAT

Elke een (1) tablet D3 1000™ bevat die volgende aktiewe:  
Vitamiën D (as cholekalsiferol) 25 µg (1000 I.E.)

**Onaktiewe bestanddele:** Lemmetjiesap poeier (*Citrus aurantifolia*), hidroksipropiëlsellulose, lemjetjie geur, sitroensuur, magnesium steeraat, silikondioksied

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

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

### WAT IS D3 1000™ EN WAARVOOR WORD DIT GEBRUIK

D3 1000™ bevat 'n hoë sterkte vitamien D3, die mees bioaktiewe vorm van vitamien D. Vitamiën D is belangrik vir die instandhouding van gesonde beensterkte en immuunfunksie.

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

D3 1000™ bevat Mannitol, steviolglikosiede, xylitol wat 'n effek op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het, en 'n lakseermiddel kan hê.

### VOORDAT JY D3 1000™ NEEM

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. **Laboratoriumtoetse:** Hierdie medisyne kan inmeng met sekere laboratoriumtoetse (soos bloedtoetse vir cholesterol), wat moontlik vals toetsresultate kan veroorsaak. Maak seker dat laboratoriumpersoneel en al jou dokters weet dat jy hierdie medisyne gebruik.

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

### SWANGERSKAP EN BORSVOEDING

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

### BESTUUR EN GEbruik VAN MASIENE

Dit is nie altyd moontlik om te voorspel in watter mate D3 1000™ die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe D3 1000™ jou beïnvloed.

### NEEM VAN ANDER MEDISYNE SAAM MET D3 1000™

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

### HOE OM D3 1000™ TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd D3 1000™ presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

### Aanwysings vir gebruik:

**Volwasse:** Kou of sluk een (1) tablet daaglik saam met etes of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER D3 1000™ NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

### AS JY VERGEET OM D3 1000™ TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

### MOONTLIKE NEWE-EFFEKTE

D3 1000™ kan newe-effekte hê.

Indien jy enige van die volgende diagnoseerde 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: burosomab, 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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

**Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):**

- naardeel / braking, hardlywigheid, verlies aan eetlus, verhoogde dorshede, verhoogde urinering, gestelike / gemoedsveranderinge, ongewone moegheid.

Nie alle newe-effekte en interaksies wat vir D3 1000™ gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

### AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aaniyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/3>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van D3 1000™.

### HOE OM D3 1000™ TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

### AANBIEDING VAN D3 1000™

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

### IDENTIFIKASIE VAN D3 1000™

Onbedekte, ronde tablet

### REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

### TOEGANG TOT DIE OOREENSTEMMende PROFESSIONELE INLIGTING

Skandeer QR-kode..

### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

### NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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