

**PROFESSIONAL INFORMATION**

(capsules)

**Complementary Medicine: Health Supplement  
 D 34.11 Vitamins**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

**SCHEDULING STATUS:** S0

**1. NAME OF THE MEDICINE  
 BIOGEN VITAMIN D3 500 IU**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:

Vitamin D3 (Cholecalciferol)	500 IU / 12,5 µg
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For a full list of excipients, see section 6.1.

Sugar free

**3. PHARMACEUTICAL FORM**

Small, round, normal concave white to off-white capsules.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**4.2 Posology and method of administration**

**Adults and children 6 years and older:** one (1) capsule daily.

**4.3 Contraindications:**

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Patients with hypercalcaemia or renal osteodystrophy with hyperphosphatemia.

**4.4 Special warnings and precautions for use**

- Vitamin D may increase calcium levels and increase the risk of arteriosclerosis in renal failure.
- Patients with calculi or heart disease should have plasma phosphate concentration carefully controlled and monitored to reduce the risk of ectopic calcification.
- Vitamin D may increase calcium levels in patients with histoplasmosis, hyperparathyroidism, sarcoidosis, and tuberculosis. The metabolism to calcitriol is increased, which may cause hypercalcaemia and complications such as kidney stones and calcified tissue.

**4.5 Interaction with other medicines and other forms of interaction**

- Some anticonvulsants (phenytoin, barbiturates, primidone) may reduce the effect of vitamin D by accelerating its metabolism.
- The effect of calcitonin may be antagonised by vitamin D.
- High doses of vitamin D can cause hypercalcaemia. Hypercalcaemia increases the risk of fatal cardiac arrhythmias with digoxin.
- Thiazide diuretics decrease urinary calcium excretion, which could lead to hypercalcaemia if vitamin D supplements are taken concurrently.
- Patients may be at increased risk of hypercalcaemia if vitamin D is given with calcium or phosphate, as vitamin D increases the active absorption of calcium and phosphorous.

**4.6 Fertility, pregnancy and lactation**

Vitamin D is likely safe when used within the recommended dosage. There is a risk of hypercalcaemic tetany in breast-fed infants whose mothers take excessive doses of vitamin D during pregnancy.

**4.7 Effects on ability to drive and use machines**

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that BIOGEN VITAMIN D3 500 IU does not adversely affect their performance.

**4.8 Undesirable effects**

*Uncommon:* Vitamin D toxicity when taken in excessive doses- symptoms include: hypercalcaemia, azotemia, and anaemia.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

**4.9 Overdose**

Overdose may lead to the development of hypercalcaemia or hyperphosphatemia, of which symptoms may include: anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo.

Treatment of overdose is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic properties**

Complementary Medicine: Health Supplement  
 D 34.11 Vitamins

**Vitamin D**

Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**5.2 Pharmacokinetic properties**
**Vitamin D**

Vitamin D is well absorbed from the gastrointestinal tract with the aid of bile. Absorption may be decreased in patients with decreased fat absorption. Vitamin D and its metabolites circulate in the blood bound to a specific  $\alpha$ -globulin. It is converted by hydroxylation, predominantly in the liver, to calcitriol, which is the main biologically active form of vitamin D. Small amounts are stored in the liver, as well as in adipose tissue. The metabolites of vitamin D analogues are excreted mainly in bile and faeces, with only small amounts appearing in urine. Although some vitamin D that is excreted in bile is reabsorbed in the small intestine, enterohepatic circulation does not appear to be an important mechanism for the conservation of the vitamin. Certain vitamin D substances may be distributed into breast milk.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**

Kollidon, micro cellulose, calcium carbonate, magnesium stearate.

**6.2 Incompatibilities**

Not applicable

**6.3 Shelf Life**

24 Months

**6.4 Special precautions for storage**

Store all medicines out of reach of children.  
 Store at or below 25 °C and protect from moisture.  
 Store in the original container.

**6.5 Nature and contents of container**

120 capsules in a white, PET plastic container and white screwcap lid.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**


Biogen  
 23 Stag Road, Glen Austin, South Africa  
 info@biogen.co.za  
 www.biogen.co.za  
 Tel: 011 589 2322

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

<b>JOB:</b> BPS_VitaminD3 500IU_120s	<b>SIZE:</b> 210mm x 280mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOUR:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dorning <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	

**PATIENT INFORMATION LEAFLET**

SCHEDULING STATUS: **S0**

**BIOGEN VITAMIN D3 500 IU**

Each capsule contains:

Vitamin D3 (Cholecalciferol)	500 IU / 12,5 µg
Sugar free	

**Complementary Medicine: Health Supplement**  
**D 34.11 Vitamins**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

**Read all of this leaflet carefully because it contains important information for you.**

BIOGEN VITAMIN D3 500 IU is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use BIOGEN VITAMIN D3 500 IU carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN VITAMIN D3 500 IU with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

**What is in this leaflet**

1. What BIOGEN VITAMIN D3 500 IU is and what it is used for.
2. What you need to know before you take BIOGEN VITAMIN D3 500 IU.
3. How to take BIOGEN VITAMIN D3 500 IU.
4. Possible side effects.
5. How to store BIOGEN VITAMIN D3 500 IU.
6. Contents of the pack and other information.

**1. What BIOGEN VITAMIN D3 500 IU is and what it is used for**

Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**2. What you need to know before you take BIOGEN VITAMIN D3 500 IU**

**Do not take BIOGEN VITAMIN D3 500 IU:**

- If you are allergic or sensitive to any of the ingredients listed in section 6.
- If you have hypercalcaemia or renal osteodystrophy with hyperphosphatemia.

**Warnings and precautions**

Consult with a healthcare practitioner prior to using BIOGEN VITAMIN D3 500 IU, especially if you have a medical condition. Use BIOGEN VITAMIN D3 500 IU with caution and consult a healthcare practitioner before use:

- If you have renal impairment, calculi, histoplasmosis, hyperparathyroidism, sarcoidosis, tuberculosis, or heart disease.

**Children and adolescents**

BIOGEN VITAMIN D3 500 IU is not recommended for children below the age of 6 years. Consult a healthcare practitioner prior to use.

**Other medicines and BIOGEN VITAMIN D3 500 IU**

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. BIOGEN VITAMIN D3 500 IU may interact with the following medications: anticonvulsants, calcitonin, digoxin, thiazide diuretics, calcium, and phosphate.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using BIOGEN VITAMIN D3 500 IU.

**Driving and using machinery**

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that BIOGEN VITAMIN D3 500 IU does not adversely affect their performance.

**3. How to take BIOGEN VITAMIN D3 500 IU**

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use BIOGEN VITAMIN D3 500 IU exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

*Adults and children older than 6 years:* Take 1 capsule daily, after a meal, or as recommended by your healthcare provider.

**4. Possible side effects**

BIOGEN VITAMIN D3 500 IU can have side effects.

Not all side effects reported for BIOGEN VITAMIN D3 500 IU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN VITAMIN D3 500 IU, please consult your doctor, pharmacist or other healthcare practitioner for advice.

If any of the following happens, stop using BIOGEN VITAMIN D3 500 IU and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to BIOGEN VITAMIN D3 500 IU. You may need urgent medical attention or hospitalisation.

**Uncommon:** vitamin D toxicity when taken in excessive doses- symptoms include:

- hypercalcaemia;
- azotemia;
- anemia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions 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 BIOGEN VITAMIN D3 500 IU.

**5. How to store BIOGEN VITAMIN D3 500 IU**

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused BIOGEN VITAMIN D3 500 IU to your pharmacist.
- Do not dispose of unused BIOGEN VITAMIN D3 500 IU in drains or sewerage systems (e.g. toilets).

**6. Contents of the pack and other information**

**What BIOGEN VITAMIN D3 500 IU contains**

Each capsule contains:

Vitamin D3 (Cholecalciferol)	500 IU / 12,5 µg
The other ingredients are kollidon, micro cellulose, calcium carbonate, magnesium stearate.	
Sugar free	

**What BIOGEN VITAMIN D3 500 IU looks like and contents of the pack**

30 small, round, concave white to off-white capsules, packed into a white plastic container.

**Holder of certificate of registration**

Biogen  
23 Stag Road, Glen Austin, South Africa  
info@biogen.co.za  
www.biogen.co.za  
Tel: 011 589 2322

**This pamphlet was last revised in**

Will be allocated by SAHPRA upon registration.

**Registration number**

Will be allocated by SAHPRA upon registration.

**PASIENTINLIGTINGSBLAD**

SKEDULERINGSSTATUS: **S0**

**BIOGEN VITAMIN D3 500 IU**

Elke kapsule contains:

Vitamen D3 (Cholekalsiferol)	500 IU / 12,5 µg
Suikervry	

**Aanvullende Medisyne: Gesondheidsaanvulling**  
**D 34.11 Vitamiene**

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

**Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.**

BIOGEN VITAMIN D3 500 IU is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet BIOGEN VITAMIN D3 500 IU versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie BIOGEN VITAMIN D3 500 IU met iemand anders deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of raad nodig het.

**Wat jy in hierdie inligtingsblad kan kry**

1. Wat is BIOGEN VITAMIN D3 500 IU en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy BIOGEN VITAMIN D3 500 IU gebruik.
3. Hoe om BIOGEN VITAMIN D3 500 IU te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN VITAMIN D3 500 IU te bère.
6. Inhoud van die verpakking en ander inligting.

**1. Wat is BIOGEN VITAMIN D3 500 IU en waarvoor word dit gebruik**

Vitamen D dra by tot die ontwikkeling en instandhouding van sterk bene en tande. Dit dra by tot die instandhouding van normale spierfunksie en dra by tot die normale funksie van die immuunsteelsel. Dit help ook met die opname en gebruik van kalsium en fosfor, normale seldeling, en is 'n faktor in die handhawing van goeie gesondheid.

**2. Wat u moet weet voordat u BIOGEN VITAMIN D3 500 IU gebruik**

**Moenie BIOGEN VITAMIN D3 500 IU gebruik nie:**

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u hiperkalsemie of nier-osteodistrofie met hiperfosfatemie het.

**Waarskuwings en voorsorgmaatreëls**

Raadpleeg 'n gesondheidsorgpraktisyn voordat u BIOGEN VITAMIN D3 500 IU gebruik, veral as u 'n mediese toestand het. Gebruik BIOGEN VITAMIN D3 500 IU met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u nierontereiktheid, calculi, histoplasiose, hiperparatiroidisme, sarkoïose, tuberkulose, of hartsiektes het.

**Kinders en adolessente**

BIOGEN VITAMIN D3 500 IU word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

**Ander medisyne saam met BIOGEN VITAMIN D3 500 IU**

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. BIOGEN VITAMIN D3 500 IU kan interaksie hê met die volgende medisyne: antikonvulsante, kalsitonien, digoksien, tiasieddiuretika, kalsium en fosfaat.

**Swangerskap, borsvoeding en vrugbaarheid**

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u BIOGEN VITAMIN D3 500 IU gebruik.

**Bestuur en die gebruik van masjinerie**

Besprek studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat BIOGEN VITAMIN D3 500 IU nie hul werkverrigting nadelig beïnvloed nie.

**3. Hoe om BIOGEN VITAMIN D3 500 IU te gebruik**

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik BIOGEN VITAMIN D3 500 IU presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

*Volwasse en kinders 6 jaar en ouer:* Neem 1 kapsule daaglik, of soos aanbeveel deur u gesondheidsorgpraktisyn.

**4. Moontlike nuwe-effekte**

BIOGEN VITAMIN D3 500 IU kan nuwe-effekte hê.

Nie alle nuwe-effekte vir BIOGEN VITAMIN D3 500 IU is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van BIOGEN VITAMIN D3 500 IU, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

As een van die volgende gebeur, hou op met die gebruik met BIOGEN VITAMIN D3 500 IU en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal;
- veluitslag of gejeuk;
- floutes.

Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op BIOGEN VITAMIN D3 500 IU gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

**Minder dikwels:** vitamen D-toksiteit wanneer dit in oormatige dosisse geneem word- simptome sluit in:

- hiperkalsemie;
- azotemie;
- anemie.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

**Rapportering van nuwe-effekte**

Bespreek dit met jou dokter of apteker indien jy nuwe-effekte ondervind. Jy kan ook nuwe-effekte by SAHPRA aanmeld deur die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies:

<http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van BIOGEN VITAMIN D3 500 IU.

**5. Hoe om BIOGEN VITAMIN D3 500 IU te bère**

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte BIOGEN VITAMIN D3 500 IU na u apteker terug.
- Moenie ongebruikte BIOGEN VITAMIN D3 500 IU in afvoerpype of rioolstelsel (bv. toilette) weggooi nie.

**6. Inhoud van die verpakking en ander inligting**

**Wat BIOGEN VITAMIN D3 500 IU bevat**

Elke kapsule bevat:

Vitamen D3 (kolekalsiferol)	500 IU / 12,5 µg
Die ander bestanddele is kollidon, mikrosellulose, kalsiumkarbonaat, magnesiumstearaat.	
Suikervry	

**Hoe BIOGEN VITAMIN D3 500 IU en die inhoud van die verpakking lyk**

30 klein, ronde, konkawe wit tot af-wit kapsules verpak in 'n wit plastiekhouer.

**Holder of certificate of registration**

Biogen  
Stagweg 23, Glen Austin, Suid Afrika  
info@biogen.co.za  
www.biogen.co.za  
Tel: 011 589 2322


**Hierdie pamflet is laas hiersien in**

Sal met registrasie deur SAHPRA toegeken word.

**Registrasienumer**

Sal met registrasie deur SAHPRA toegeken word.

80725 P01

<b>JOB:</b> BPS_VitaminD3 500IU_120s	<b>SIZE:</b> 210mm x 280mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOUR:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornimg <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	