

PROFESSIONAL INFORMATION
 D 34.12 Multiple substance formulation: Health Supplement

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 & COCONUT OIL soft gelatine capsules.

 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each BIOGEN VITAMIN D₃ & COCONUT OIL soft gelatine capsule contains:

Vitamin D ₃ (as cholecalciferol)	25 µg (1000 IU)
<i>Cocos nucifera</i> L. (Coconut) oil	1 000 mg

BIOGEN VITAMIN D₃ & COCONUT OIL contains sugar: glycerol (0,13 g) and sorbitol (0,015 g) per capsule.

 3. PHARMACEUTICAL FORM

Soft Gelatine Capsules.

 4. CLINICAL PARTICULARS
 4.1 Therapeutic indications

BIOGEN VITAMIN D₃ & COCONUT OIL supports healthy functioning of the immune system. It also contributes to the development and maintenance of strong bones and normal muscle function. BIOGEN VITAMIN D₃ & COCONUT OIL additionally contains coconut oil which is a source of antioxidants. Coconut oil also creates an oily environment which assists with the absorption of Vitamin D₃.

 4.2 Posology and method of administration

Adults and children: Take 1 capsule daily. Take with water after food. BIOGEN VITAMIN D₃ & COCONUT OIL may be taken continuously.

 4.3 Contraindications

BIOGEN VITAMIN D₃ & COCONUT OIL is contraindicated:

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.
- In patients with disturbances of calcium metabolism, e.g. hypercalcaemia.
- Patients with hypercholesterolemia since coconut oil may elevate cholesterol levels.

 4.4 Special warnings and precautions for use

BIOGEN VITAMIN D₃ & COCONUT OIL should be used with care in:

- Patients with hypercholesterolemia since coconut oil may elevate cholesterol levels.
- Vitamins and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN VITAMIN D₃ & COCONUT OIL.
- BIOGEN VITAMIN D₃ & COCONUT OIL contains glycerol and sorbitol. Patients with the rare hereditary condition of intolerance to glycerol or sorbitol should not take BIOGEN VITAMIN D₃ & COCONUT OIL.

 4.5 Interaction with other medicines and other forms of interaction

BIOGEN VITAMIN D₃ & COCONUT OIL may interact with the following medicines. Caution is advised when used concurrently:

Diuretics: The use of Vitamin D₃, as in BIOGEN VITAMIN D₃ & COCONUT OIL, with thiazide diuretics may contribute to hypercalcaemia.

 4.6 Fertility, pregnancy and lactation

BIOGEN VITAMIN D₃ & COCONUT OIL is safe to use in pregnancy and lactation.

 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 & COCONUT OIL does not adversely affect their performance.

 4.8 Undesirable effects

Immune system disorders:

Frequent: Hypersensitivity reactions

Gastrointestinal disorders:

Less frequent: abdominal cramps, nausea and diarrhoea.

Excessive doses of BIOGEN VITAMIN D₃ & COCONUT OIL may increase the risk of experiencing side effects (see "SIDE EFFECTS").

Long term excessive doses may lead to the development of hypercalcaemia which is characterized by the following symptoms: thirst, polyuria, anorexia, constipation, muscle weakness, fatigue, confusion, and in severe cases nausea and vomiting.

 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

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. Treatment of overdose is symptomatic and supportive. The use of BIOGEN VITAMIN D₃ & COCONUT OIL must be discontinued immediately.

 5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.12 Multiple Substance Formulation. **Complementary Medicine: Health Supplement.**

 5.1 Pharmacodynamic properties

Pharmacokinetic properties:

BIOGEN VITAMIN D₃ & COCONUT OIL consists out of a combination of vitamin D₃ and coconut oil (*Cocos nucifera* L.). Vitamin D₃ is well absorbed from the gastrointestinal tract. The presence of bile is essential for sufficient intestinal absorption. Vitamin D₃ can be stored in adipose and muscle tissue for long periods of time and has a slow onset and long duration of action. It is metabolised in the liver and kidneys to form the active metabolites. Vitamin D₃ and its metabolites are excreted mainly in the bile and faeces.

Pharmacodynamic properties:

Coconut oil (*Cocos nucifera* L.) is a source of antioxidants which protects cells against the damaging effects of free radicals. Coconut oil also creates a fatty environment which improves the absorption of Vitamin D₃ due to its lipophilic nature. Vitamin D₃ plays an important role in calcium homeostasis and contributes to the development and maintenance of strong bones by assisting with the absorption and use of calcium and phosphorous in the body. It further contributes to the maintenance of normal muscle function by increasing muscle strength and neuromuscular function. Vitamin D₃ also plays an important role in maintaining healthy immune function.

 6. PHARMACEUTICAL PARTICULARS
 6.1 List of excipients

The inactive ingredients are gelatine (bovine), glycerine, iron oxide yellow, purified water, simethicone, sorbitol 70 %, sunflower seed oil and titanium dioxide.

 6.2 Incompatibilities

Not applicable.

 6.3 Shelf Life

24 Months.

 6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

 6.5 Nature and contents

An oblong, off-white soft gelatine capsule.

250 ml white PET container with a Biogen cap.

Pack size: 60 soft gelatine capsules.

 6.6 Special precautions for disposal

No special requirements.

 7. HOLDER OF CERTIFICATE OF REGISTRATION

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 Glen Austin, South Africa
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 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

 10. DATE OF REVISION OF THE TEXT

December 2022.