

PROFESSIONAL INFORMATION

GRACE VIT D3 VECECAPS

SCHEDULING STATUS

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PROPRIETARY NAME (and dosage form)

GRACE VIT D3 VECECAPS

COMPOSITION

Each vegecap contains:	per vegecap	% NRV (1)
Vitamin D3	1000 IU	166

(1) South African Nutrient Reference Values for individuals 37 months and over

Inactive ingredients: Magnesium stearate, Microcrystalline cellulose, Aerosil 2000

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine, Health Supplement
Vitamins

PHARMACOLOGICAL ACTION

Vitamin D is responsible for the absorption and use of both calcium and phosphorus in the body. In addition, it ensures the control of normal blood calcium levels. The mechanism by which Vitamin D acts to maintain normal concentrations of calcium and phosphorus in the plasma is to facilitate their absorption from the small intestine, to interact with parathyroid hormone to allow the mobilisation of these 2 minerals from bone and to decrease their excretion by the kidney.

Vitamin D is essential for the development and maintenance of strong and healthy bones and teeth; normal cell division; the maintenance of normal neuromuscular function and the maintenance and function of a healthy immune system. Calcium intake combined with sufficient levels of vitamin D3, a healthy diet and regular exercise may reduce the risk of developing osteoarthritis.

INDICATIONS

The role of nutrition to promote good health is beyond debate. Vitamin and mineral supplements are generally indicated to combat specific deficiencies where diet is known to be inadequate and should be regarded as a temporary intervention until a healthy balanced diet can be reinstated.

Grace Vit D3 vegecaps are recommended for individuals who have a vitamin D deficiency due to insufficient dietary intake or exposure to natural sunlight. In the elderly, vitamin D absorption from sunlight may be reduced and supplementation may be of benefit.

CONTRAINDICATIONS

- Individuals with a hypersensitivity to calciferol or any of the active or inactive ingredients
- Individuals with hypercalcaemia and hypercalciuria
- Patients suffering from nephrolithiasis
- Patients with severe renal impairment
- Patients suffering from hypervitaminosis

WARNINGS

Grace Vit D3 is a vitamin and mineral supplement and is not a replacement for a healthy balanced diet.

Do not exceed the recommended dosage of 1 capsule per day, unless prescribed by a Healthcare Practitioner.

Individuals who have a medical condition, or are taking other medication, must consult with a Healthcare Practitioner before taking Grace Vit D3, as they may have special requirements.

Individuals with heart disease, kidney disease, an electrolyte imbalance, diabetes or phenylketonuria should not take Grace Vit D3 without first consulting a Healthcare Practitioner.

Grace Vit D3 should not be taken if individuals are allergic to, or have a hypersensitivity to any of the ingredients.

Adequate levels of dietary calcium are required for a clinical response to vitamin D therapy however a Healthcare Practitioner should be consulted if the patient is taking a calcium supplement before starting to take Grace Vit D3.

The effects of Grace Vit D3 may be reduced in patients taking barbiturates or anticonvulsants; or individuals who have had gastric bypass surgery; severe shortening or inflammation of the small intestine; hepatic or biliary dysfunction. Dietary supplementation may be harmful to individuals who are already receiving an adequate intake of vitamin D through their diet and exposure to sunlight.

INTERACTIONS

If patients are currently taking any medication, health supplements, or are being treated for any condition their Healthcare Practitioner should be consulted before taking this product.

Potential interactions may occur with the following medications, in particular:

- Diuretics
- Antacids, particularly if the patient has kidney disease
- Cardiac drugs, particularly digoxin and calcium channel blockers
- Cholesterol lowering medication, particularly statins
- Anticonvulsants
- Clarithromycin
- Cyclosporine
- Estrogens
- Indinavir
- Triazolam
- Calcium Supplementation

PREGNANCY AND LACTATION

Safety in pregnancy and in breastfeeding women has not been established.

DOSAGE AND DIRECTIONS FOR USE

Take 1 capsule daily after a meal with a glass of water.

DO NOT EXCEED THIS DOSE UNLESS UNDER THE SUPERVISION OF A HEALTHCARE PRACTITIONER.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

When taken in the prescribed dosage and as directed, there have been no reports of major adverse events and side effects.

Possible side effects may include:

- Cardiac disorders – dysrhythmias, hypertension
- Metabolic disorders – hypercalcaemia
- Renal disease – calciuria
- Dermatological conditions – pruritis, rash, urticaria, hives, itching
- Gastrointestinal disorders – nausea, vomiting, diarrhoea, metallic taste in mouth
- Hypersensitivity – angioedema, laryngeal oedema
- Musculoskeletal conditions – unusual tiredness and muscular weakness

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Vitamin D3 is the most likely vitamin to cause toxicity due to overdosage as the difference between the therapeutic and toxic dose is narrow. Doses in excess of the patient's daily requirement can cause hypercalcaemia, hypercalciuria and hyperphosphataemia

In cases of suspected overdosage, immediate withdrawal of the product is indicated and the patient should receive immediate medical attention from a Healthcare Practitioner.

IDENTIFICATION

Grace Vit D vegecaps are white on white, size 0, vegecaps and are filled with a white powder.

PRESENTATION

Grace Vit D vegecaps are packed in white securitainers containing 60 vegecaps each.

STORAGE INSTRUCTIONS

Store in a cool dry place below 25 °C, away from direct sunlight. Keep the container firmly closed at all times.

KEEP OUT OF REACH OF CHILDREN AND UNINFORMED INDIVIDUALS

This product has not been evaluated by SAPHRA. This product is not intended to diagnose, treat, cure or prevent disease.

NAME AND BUSINESS ADDRESS OF APPLICANT

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