

PROFESSIONAL INFORMATION
NATIVA COMPLEX® VITAMIN D₃ 1000 IU

- Complementary Medicine
- Discipline: D.34.11 Complementary Medicine: Health Supplement-Vitamins
- Health Supplements are intended only to complement health or supplement the diet. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

[S0]

1. NAME OF THE MEDICINE

NATIVA COMPLEX® VITAMIN D₃ 1000 IU (capsule)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active Ingredients	per capsule (maximum daily dosage)
Vitamin D ₃ (cholecalciferol)	1000 IU (25 µg)

Nativa Complex® Vitamin D₃ 1000 IU is sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard gelatine

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® Vitamin D₃ 1000 IU is intended for the support of immune function and for the maintenance of healthy bones and teeth. Vitamin D₃ helps the absorption of calcium and phosphorous. Calcium intake, when combined with sufficient vitamin D₃, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

4.2 Posology and method of administration

The recommended daily dosage is

Adults and children 6 years and older:

Take One (1) capsule per day, after a meal with a glass of water.

4.3 Contraindications

Hypersensitivity to the active substance, Vitamin D₃, or any of the other ingredients of Nativa Complex® Vitamin D₃ 1000 IU (see section 6.1 List of excipients).

4.4 Special warnings and precautions for use

- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients. Patients should be advised to consult their medical practitioner if in doubt.
- Patients with renal calculi, renal impairment, or a history of these conditions, should use this product with caution, as Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃.
- Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃ which can aggravate conditions such as hypercalcemia and/or hypercalciuria.
- Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃ which can worsen hyperphosphatemia.

Porphyria

Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Active ingredient	Medicine	Description
Vitamin D ₃	Calcium supplements	Vitamin D ₃ has the potential to increase the absorption of calcium when used concomitantly with calcium supplements.

4.6 Fertility, pregnancy and lactation

Excess vitamin D₃ is not recommended during pregnancy or lactation without medical supervision.

Pregnancy

At the healthcare provider's discretion, vitamin D₃ supplementation can form part of a medically supervised and managed supplementation programme, during pregnancy.

Breastfeeding

Vitamin D₃ supplementation is suitable for use during lactation at the recommended dose and under the supervision of a healthcare provider.

Fertility

There are no known effects of Nativa Complex® Vitamin D₃ 1000 IU on fertility.

4.7 Effects on the ability to drive and use machines.

Based on the side effect profile, Nativa Complex® Vitamin D₃ 1000 IU is not expected to affect the ability to drive or operate machinery.

4.8 Undesirable effects

Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.

System Organ Class	Frequency	Adverse Event
Gastrointestinal Disorders	frequency unknown	Abdominal discomfort, constipation, diarrhoea, dry mouth, loss of appetite, nausea, vomiting

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product 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

Symptoms:

See **4.8 Undesirable effects**

There is no evidence that this product can lead to an overdose when used as recommended.

Treatment

If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D.34.11 Complementary Medicine: Health Supplement-Vitamins

Pharmacotherapeutic classification: Vitamin D and analogues

ATC code: A11CC

Vitamin D₃ is a fat-soluble vitamin and appears to have immunological activity. It is also an essential vitamin for the proper regulation of calcium and phosphate homeostasis and bone mineralisation.

5.2 Pharmacokinetic properties

Vitamin D₃ is well absorbed from the gastrointestinal tract and can be stored in adipose tissue. Vitamin D₃ and cholecalciferol are hydroxylated in the liver to form calcifediol and thereafter, undergoes further hydroxylation in the kidneys to form the active metabolite calcitriol. Vitamin D and its metabolites are primarily excreted in the bile and faeces, with only small quantities appearing in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine capsule (bovine)

Magnesium stearate

Maize starch

Silicon dioxide

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until required for use.

6.5 Nature and contents of container

Nativa Complex® Vitamin D₃ 1000 IU are orange capsules.

Nativa Complex® Vitamin D₃ 1000 IU are available in a white high density polyethylene plastic container with a turquoise polypropylene flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd

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Customer care line: 0860 628 482

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8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT