

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

Proprietary name and dosage form

NATIVA COMPLEX® VITAMIN D₃ 1000 IU capsule

Vitamin D₃ (cholecalciferol)

Sugar free.

- D 34.11 Health Supplements - 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.

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

Nativa Complex® Vitamin D₃ 1000 IU is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Vitamin D₃ 1000 IU carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share Nativa Complex® Vitamin D₃ 1000 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 Nativa Complex® Vitamin D₃ 1000 IU is and what it is used for
2. What you need to know before you take Nativa Complex® Vitamin D₃ 1000 IU
3. How to take Nativa Complex® Vitamin D₃ 1000 IU
4. Possible side effects
5. How to store Nativa Complex® Vitamin D₃ 1000 IU
6. Contents of the pack and other information

1. What Nativa Complex® Vitamin D₃ 1000 IU is and what it is used for

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.

2. What you need to know before you take Nativa Complex® Vitamin D₃ 1000 IU

Do not take Nativa Complex® Vitamin D₃ 1000 IU:

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Vitamin D₃ 1000 IU (see section 6).

Warnings and precautions

- Consult a healthcare provider prior to use if you have kidney stones, have a history of kidney stones or renal impairment as Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃.
- Consult a healthcare provider prior to use if you have high levels of calcium in your blood (hypercalcemia) or in your urine (hypercalciuria) as Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃ which can worsen the conditions.
- Consult a healthcare provider prior to use if you have high levels of phosphate in your blood (hyperphosphatemia) as Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃ which can worsen hyperphosphatemia.

Tell your doctor if you are not sure about any of the above.

Porphyria: Safety has not been established.

Other medicines and Nativa Complex® Vitamin D₃ 1000 IU

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Calcium supplements as Nativa Complex® Vitamin D₃ 1000 IU contains vitamin D₃ which can increase the absorption of calcium.

Taking Nativa Complex® Vitamin D₃ 1000 IU with food and drink

You should take Nativa Complex® Vitamin D₃ 1000 IU after a meal, with a glass of water.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before taking this medication. If you require extra vitamin D do not take it without medical supervision because too much vitamin D may harm your baby.

Driving and using machinery

Nativa Complex® Vitamin D₃ 1000 IU should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

3. How to take Nativa Complex® Vitamin D₃ 1000 IU

Do not share medicines with any other person.

Always take Nativa Complex® Vitamin D₃ 1000 IU exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor or pharmacist regarding the recommended dosage if you are unsure.

The usual dose for adults and children 6 years and older is:

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

If you take more Nativa Complex® Vitamin D₃ 1000 IU than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to take Nativa Complex® Vitamin D₃ 1000 IU

Take your missed dose when you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and revert to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Nativa Complex® Vitamin D₃ 1000 IU

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

Nativa Complex® Vitamin D₃ 1000 IU can have side effects.

Not all side effects reported for Nativa Complex® Vitamin D₃ 1000 IU are included in this leaflet.

Should your general health worsen while taking this medicine, or if you experience any undesired effects while taking Nativa Complex® Vitamin D₃ 1000 IU, please consult your healthcare provider for advice.

Like all medicines, this medicine can cause side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following:

Frequency unknown:

- Abdominal discomfort, constipation, diarrhoea, dry mouth, loss of appetite, nausea, vomiting.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, nurse or other healthcare provider for advice. You can also report side effects to SAHPRA via the “**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 Nativa Complex® Vitamin D₃ 1000 IU.

5. How to store Nativa Complex® Vitamin D₃ 1000 IU

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Keep the container tightly closed.
- Protect from light.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Nativa Complex® Vitamin D₃ 1000 IU contains

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

The other ingredients are: gelatin capsule (bovine), magnesium stearate, maize starch, silicon dioxide.

Nativa Complex® Vitamin D₃ 1000 IU is sugar free.

What Nativa Complex® Vitamin D₃ 1000 IU looks like and contents of the pack

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

Holder of Certificate of Registration

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This leaflet was last revised in

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

Nativa Complex® Vitamin D₃ 1000 IU Professional Information may be obtained from the Nativa website (www.nativa.co.za).