PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX VITAMIN D3 1000 IU hard capsules

Vitamin D3 (cholecalciferol) 25 micrograms (1 000 IU) per daily dose (1 capsule)
Sugar free

COMPLEMENTARY MEDICINE
Health Supplement
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet is also available in Afrikaans at https://genologix.co.za/product/genologix-vitamin-d3-1000-iu-25mcg-bulk-120-days-supply/

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

Genologix Vitamin D3 1000 IU is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix 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 Genologix Vitamin D3 1000 IU with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Genologix Vitamin D3 1000 IU is and what it is used for
2. What you need to know before you take Genologix Vitamin D3 1000 IU
3. How to take Genologix Vitamin D3 1000 IU
4. Possible side effects
5. How to store Genologix Vitamin D3 1000 IU
6. Contents of the pack and other information

1. What Genologix Vitamin D3 1000 IU is and what it is used for

Genologix Vitamin D3 1000 IU is a health supplement. It contains vitamin D3 (cholecalciferol) from a plant-based (lichen) source, suitable for vegans.

Your skin makes vitamin D when exposed to sunlight. It is also found in a few foods, such as oily fish and eggs.

Genologix Vitamin D3 1000 IU:

- contributes to the normal function of the immune system;
- contributes to the development and maintenance of strong bones and teeth;
- helps in the absorption and use of calcium and phosphorus;
- contributes to the maintenance of normal muscle function; and
- is a factor in the maintenance of good health.

2. What you need to know before you take Genologix Vitamin D3 1000 IU

Do not take Genologix Vitamin D3 1000 IU:

- if you are hypersensitive (allergic) to vitamin D3 (cholecalciferol) or any of the other ingredients of Genologix Vitamin D3 1000 IU (listed in section 6).
- if you have high levels of calcium in your blood or urine;
- if you have high levels of vitamin D in your blood.

Warnings and precautions

Take special care with Genologix Vitamin D3 1000 IU. Talk to your doctor or pharmacist before taking it:

- if you have kidney disease or kidney stones;
- if you have sarcoidosis, an overactive parathyroid gland, or another condition that can raise calcium levels;
- if you take any of the medicines listed under "Other medicines and Genologix Vitamin D3 1000 IU".

Vitamin D from other supplements (such as multivitamins or fish liver oils) should be taken into account when taking Genologix Vitamin D3 1000 IU.

Children and adolescents

Do not give Genologix Vitamin D3 1000 IU to children and adolescents under 18 years of age. Its safety in this age group has not been established.

Other medicines and Genologix Vitamin D3 1000 IU

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

Talk to your doctor or pharmacist before you take Genologix Vitamin D3 1000 IU if you take:

- thiazide diuretics ("water tablets", e.g. hydrochlorothiazide), because calcium levels may rise too high;
- digoxin (a heart medicine);
- medicines for epilepsy (e.g. phenytoin, carbamazepine) or corticosteroids, which may lower vitamin D levels;
- orlistat (a weight-loss medicine), which may reduce vitamin D absorption.

Genologix Vitamin D3 1000 IU with food, drink and alcohol

Take Genologix Vitamin D3 1000 IU with food. Vitamin D is absorbed best with a meal that contains some fat.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, consult your health care provider before taking Genologix Vitamin D3 1000 IU.

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 health care provider for advice before taking this medicine.

Driving and using machines

Genologix Vitamin D3 1000 IU is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Vitamin D3 1000 IU may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Vitamin D3 1000 IU affects you.

Genologix Vitamin D3 1000 IU contains

Genologix Vitamin D3 1000 IU contains no sugar and no sweeteners.

3. How to take Genologix Vitamin D3 1000 IU

Do not share medicines prescribed for you with any other person.

Always take Genologix Vitamin D3 1000 IU exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (18 years and older): take one (1) capsule once a day. This provides 25 micrograms (1 000 IU) of vitamin D3.

Do not take more than one (1) capsule in 24 hours.

Children and adolescents under 18 years: Genologix Vitamin D3 1000 IU is not intended for this age group.

How to take it:

1. Take the capsule with a meal.
2. Swallow the capsule whole with a glass of water.
3. Stop taking Genologix Vitamin D3 1000 IU if you get any side effects (see section 4).

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you take more Genologix Vitamin D3 1000 IU than you should

Taking too much vitamin D over a long time can raise calcium levels in the blood. Signs include nausea, vomiting, loss of appetite, constipation, weakness, confusion, increased thirst and passing more urine.

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

If you forget to take Genologix Vitamin D3 1000 IU

If you forget a dose, take your next dose at the usual time the next day.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Genologix Vitamin D3 1000 IU

You can stop taking Genologix Vitamin D3 1000 IU at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Vitamin D3 1000 IU can have side effects.

Not all side effects reported for Genologix Vitamin D3 1000 IU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Vitamin D3 1000 IU, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Vitamin D3 1000 IU and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to Genologix Vitamin D3 1000 IU. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown (usually only with long-term high intakes):

- nausea (feeling sick) or loss of appetite,
- constipation,
- increased thirst or passing more urine,
- tiredness or weakness.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Vitamin D3 1000 IU.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

5. How to store Genologix Vitamin D3 1000 IU

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep the capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Vitamin D3 1000 IU if the pouch seal is broken or the capsules look damaged.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Genologix Vitamin D3 1000 IU contains

The active substance is vitamin D3 (cholecalciferol), from lichen.

Active ingredient	Per capsule	Per daily dose (1 capsule)
Cholecalciferol (vitamin D3) [lichen]	25 µg (1 000 IU)	25 µg (1 000 IU)

The other ingredients are microcrystalline cellulose, magnesium stearate and hypromellose (the vegan capsule shell). The vitamin D3 is supplied as a powder (100 000 IU per gram) on a carrier.

Microcrystalline cellulose is a plant fibre used as a filler. It makes sure that every capsule contains the correct amount of the active ingredient. Magnesium stearate is a common ingredient in foods and medicines. A very small amount is used to help the powder flow smoothly through our production machines. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

What Genologix Vitamin D3 1000 IU looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a white to off-white powder.

120 capsules (120 daily doses) packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

Access to the corresponding Professional Information

The Professional Information for Genologix Vitamin D3 1000 IU is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.