

**PROFESSIONAL INFORMATION**

**D 34.11 Vitamins. Complementary Medicine: 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**

LOCAL HEALTH VITAMIN D 1000 IU tablets

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains:

Cholecalciferol (Vitamin D3)	1000 IU / 25 µg
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**Sugar free**

For full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Small, round, normal concave white to off-white tablets.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**4.2 Posology and method of administration**

Adults and children 6 years and older: one (1) tablet daily.

**4.3 Contraindications**

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Patients with hypercalcaemia or renal osteodystrophy with hyperphosphatemia.

**4.4 Special warnings and precautions for use**

- Vitamin D may increase calcium levels and increase the risk of arteriosclerosis in renal failure.
- Patients with calculi or heart disease should have plasma phosphate concentration carefully controlled and monitored to reduce the risk of ectopic calcification.
- Vitamin D may increase calcium levels in patients with histoplasmosis, hyperparathyroidism, sarcoidosis, and tuberculosis. The metabolism to calcitriol is increased, which may cause hypercalcemia and complications such as kidney stones and calcified tissue.

**4.5 Interaction with other medicines and other forms of interaction**

- Some anticonvulsants (phenytoin, barbiturates, primidone) may reduce the effect of vitamin D by accelerating its metabolism.
- The effect of calcitonin may be antagonised by vitamin D.
- High doses of vitamin D can cause hypercalcaemia. Hypercalcaemia increases the risk of fatal cardiac arrhythmias with digoxin.
- Thiazide diuretics decrease urinary calcium excretion, which could lead to hypercalcaemia if vitamin D supplements are taken concurrently.
- Patients may be at increased risk of hypercalcaemia if vitamin D is given with calcium or phosphate, as vitamin D increases the active absorption of calcium and phosphorus.

**4.6 Fertility, pregnancy and lactation**

Vitamin D is likely safe when used within the recommended dosage. There is a risk of hypercalcaemic tetany in breast-fed infants whose mothers take excessive doses of vitamin D during pregnancy.

**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 LOCAL HEALTH VITAMIN D 1000 IU does not adversely affect their performance.

**4.8 Undesirable effects**

**Less frequent:** Vitamin D toxicity when taken in excessive doses- symptoms include: hypercalcaemia, azotemia, and anaemia.

**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**

Overdose may lead to the development of hypercalcaemia or hyperphosphatemia, of which symptoms may include: anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Treatment of overdose is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

**Vitamin D** contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**5.2 Pharmacokinetic properties**

**Vitamin D** is well absorbed from the gastrointestinal tract with the aid of bile. Absorption may be decreased in patients with decreased fat absorption. Vitamin D and its metabolites circulate in the blood bound to a specific  $\alpha$ -globulin. It is converted by hydroxylation, predominantly in the liver, to calcitriol, which is the main biologically active form of vitamin D. Small amounts are stored in the liver, as well as in adipose tissue. The metabolites of vitamin D analogues are excreted mainly in bile and faeces, with only small amounts appearing in urine. Although some vitamin D that is excreted in bile is reabsorbed in the small intestine, enterohepatic circulation does not appear to be an important mechanism for the conservation of the vitamin. Certain vitamin D substances may be distributed into breast milk.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Kollidon, micro cellulose, calcium carbonate, magnesium stearate.

**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.

KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

30 tablets in a white, PET plastic container and white screwcap lid.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

011 589 2729

www.localhealth.com

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET  
SCHEDULING STATUS**

S0  
**LOCAL HEALTH VITAMIN D 1000 IU (tablets)**

Each tablet contains:	
Cholecalciferol (Vitamin D3)	1000 IU / 25 µg

Sugar free

**Complementary Medicine: Vitamins (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.

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

LOCAL HEALTH VITAMIN D 1000 IU is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH VITAMIN D 1000 IU carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH VITAMIN D 1000 IU with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

**What is in this leaflet**

1. What LOCAL HEALTH VITAMIN D 1000 IU is and what it is used for.
2. What you need to know before you use LOCAL HEALTH VITAMIN D 1000 IU.
3. How to use LOCAL HEALTH VITAMIN D 1000 IU.
4. Possible side effects.
5. How to store LOCAL HEALTH VITAMIN D 1000 IU.
6. Contents of the pack and other information.

**1. What LOCAL HEALTH VITAMIN D 1000 IU is and what it is used for**

Vitamin D contributes to the development and maintenance of strong bones and teeth. It contributes to the maintenance of normal muscle function, and contributes to the normal function of the immune system. It also assists in the absorption and use of calcium and phosphorus, to normal cell division, and is a factor in the maintenance of good health.

**2. What you need to know before you use LOCAL HEALTH VITAMIN D 1000 IU**

**Do not use LOCAL HEALTH VITAMIN D 1000 IU:**

- If you are allergic or sensitive to any of the ingredients listed in section 6.
- If you have hypercalcaemia or renal osteodystrophy with hyperphosphatemia.

**Warnings and precautions**

Consult with a healthcare practitioner prior to using LOCAL HEALTH VITAMIN D 1000 IU, especially if you have a medical condition.

Use LOCAL HEALTH VITAMIN D 1000 IU with caution and consult a healthcare practitioner before use:

- If you have renal impairment, calculi, histoplasmosis, hyperparathyroidism, sarcoidosis, tuberculosis, or heart disease.

**Children and adolescents**

LOCAL HEALTH VITAMIN D 1000 IU is not recommended for children below the age of 6 years. Consult a healthcare practitioner prior to use.

**Other medicines and LOCAL HEALTH VITAMIN D 1000 IU**

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH VITAMIN D 1000 IU may interact with the following medications: anticonvulsants, calcitonin, digoxin, thiazide diuretics, calcium, and phosphate.

**Pregnancy, breastfeeding and fertility**

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 healthcare practitioner for advice before using LOCAL HEALTH VITAMIN D 1000 IU.

**Driving and using machinery**

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 LOCAL HEALTH VITAMIN D 1000 IU does not adversely affect their performance.

**3. How to use LOCAL HEALTH VITAMIN D 1000 IU**

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH VITAMIN D 1000 IU exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 6 years and older:

Take one (1) tablet daily, or as recommended by a healthcare practitioner.

**4. Possible side effects**

LOCAL HEALTH VITAMIN D 1000 IU can have side effects. Not all side effects reported for LOCAL HEALTH VITAMIN D 1000 IU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH VITAMIN D 1000 IU, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH VITAMIN D 1000 IU and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH VITAMIN D 1000 IU. You may need urgent medical attention or hospitalisation.

- **Less frequent:** vitamin D toxicity when taken in excessive doses- symptoms include: hypercalcaemia, azotemia, and anemia.

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

**Reporting of side effects**

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH VITAMIN D 1000 IU.

**5. How to store LOCAL HEALTH VITAMIN D 1000 IU**

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH VITAMIN D 1000 IU to your pharmacist.
- Do not dispose of unused LOCAL HEALTH VITAMIN D 1000 IU in drains or sewerage systems (e.g. toilets).

**6. Contents of the pack and other information**

**What LOCAL HEALTH VITAMIN D 1000 IU contains**

Each tablet contains:	
Cholecalciferol (Vitamin D3)	1000 IU / 25 µg

Other ingredients: Kollidon, micro cellulose, calcium carbonate, magnesium stearate.  
Sugar free

**Presentation and identification of LOCAL HEALTH VITAMIN D 1000 IU**

30 small, round, concave white to off-white tablets, packed into a white plastic container.

**Holder of Certificate of Registration**

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685  
Careline: 011 589 2729; [careline@cjsa.com](mailto:careline@cjsa.com); [www.localhealth.co.za](http://www.localhealth.co.za)

**This pamphlet was last revised in**

Will be allocated by SAHPRA upon registration.

**Registration number**

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD  
SKEDULERINGSSTATUS**

S0  
**LOCAL HEALTH VITAMIN D 1000 IU (tablette)**

Elke tablet bevat:	
Cholekalsiferol (Vitamiën D3)	1000 IU / 25 µg

Suikervry

**Komplementêre Medisyne: Vitamiene (Gesondheidsaanvulling)**

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

**Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.**

LOCAL HEALTH VITAMIN D 1000 IU is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH VITAMIN D 1000 IU versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH VITAMIN D 1000 IU met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

**Wat is in hierdie inligtingsblad**

1. Wat LOCAL HEALTH VITAMIN D 1000 IU is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN D 1000 IU gebruik.
3. Hoe om LOCAL HEALTH VITAMIN D 1000 IU te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH VITAMIN D 1000 IU.
6. Inhoud van die verpakking en ander inligting.

**1. Wat LOCAL HEALTH VITAMIN D 1000 IU is en waarvoor dit gebruik word**

Vitamiën D dra by tot die ontwikkeling en instandhouding van sterk bene en tande. Dit dra by tot die instandhouding van normale spierfunksie en dra by tot die normale funksie van die immuunstelsel. Dit help ook met die opname en gebruik van kalsium en fosfor, normale seldeling, en is 'n faktor in die handhawing van goeie gesondheid.

**2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN D 1000 IU gebruik**

**Moet nie LOCAL HEALTH VITAMIN D 1000 IU neem nie:**

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u hiperkalsemie of nier-osteodistrofie met hiperfosfatemie het.

**Waarskuwings en voorsorgmaatreëls**

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH VITAMIN D 1000 IU gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH VITAMIN D 1000 IU met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u nierontoereiktheid, calculi, histoplasmose, hiperparatiroïedisme, sarkoïose, tuberkulose, of hartsiektes het.

**Kinders en adolessente**

LOCAL HEALTH VITAMIN D 1000 IU word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

**Die neem van LOCAL HEALTH VITAMIN D 1000 IU en ander medisyne**

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH VITAMIN D 1000 IU kan interaksie hê met die volgende medisyne: antikonvulsante, kalsitonien, digoksien, tiasieddiuretika, kalsium en fosfaat.

**Swangerskap, borsvoeding en vrugbaarheid**

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH VITAMIN D 1000 IU gebruik.

**Bestuur en die gebruik van masjinerie**

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Patiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH VITAMIN D 1000 IU nie hul werkverrigting nadelig beïnvloed nie.

**3. Hoe om LOCAL HEALTH VITAMIN D 1000 IU te gebruik**

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbevelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH VITAMIN D 1000 IU presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 6 jaar en ouer:

Neem een (1) tablet daaglik, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

**4. Moontlike nuwe-effekte**

LOCAL HEALTH VITAMIN D 1000 IU kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH VITAMIN D 1000 IU is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewensde reaksies ervaar tydens die gebruik van LOCAL HEALTH VITAMIN D 1000 IU, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH VITAMIN D 1000 IU en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH VITAMIN D 1000 IU gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Minder dikwels:** vitamiën D-toksiteit wanneer dit in oormatige dosisse geneem word- simptome sluit in: hiperkalsemie, azotemie en anemie.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

**Rapportering van nuwe-effekte**

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH VITAMIN D 1000 IU.

**5. Berging van LOCAL HEALTH VITAMIN D 1000 IU**

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BIJTE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH VITAMIN D 1000 IU na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH VITAMIN D 1000 IU in afvoerpepe of rioolsisteme (bv. toilette) weggooi nie.

**6. Inhoud van die verpakking en ander inligting**

**Wat LOCAL HEALTH VITAMIN D 1000 IU bevat**

Elke tablet bevat:	
Cholekalsiferol (Vitamiën D3)	1000 IU / 25 µg

Ander bestanddele: Kollidon, mikrosellulose, kalsiumkarbonaat, magnesiumstearaat.  
Suikervry

**Aanbieding en identifikasie van LOCAL HEALTH VITAMIN D 1000 IU**

30 klein, ronde, konkawe wit tot af-wit tablette verpak in 'n wit plastiekhouer.

**Houer van Registrasiesertifikaat**

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685  
Sorglyn: 011 589 27293; [careline@cjsa.com](mailto:careline@cjsa.com); [www.localhealth.co.za](http://www.localhealth.co.za)

**Hierdie pamflet is laas hersien in**

Sal met registrasie deur SAHPRA toegeken word.

**Registrasienummer**

Sal met registrasie deur SAHPRA toegeken word.