

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 B-COMPLEX tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Nicotinamide (Vitamin B3)	16 mg
Pantothenic Acid (Vitamin B5)	5 mg
Pyridoxine (Vitamin B6)	1,7 mg
Riboflavin (Vitamin B2)	1,3 mg
Thiamine (Vitamin B1)	1,2 mg
Folic Acid (Vitamin B9)	400 µg
Biotin (Vitamin B7)	30 µg
Cyanocobalamin (Vitamin B12)	2,4 µg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Round, white tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH B-COMPLEX contains a combination of B-vitamins which support the normal functioning of the nervous system, contribute to the reduction of tiredness and fatigue, supports energy-yielding metabolism and which play a role in the maintenance of good health.

4.2 Posology and method of administration

Adults and children 14 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 who are hypersensitive or allergic to cobalamin or cobalt.
- Patients who have a suspected but undiagnosed vitamin B12 deficiency. Folic acid can mask pernicious anemia by decreasing megaloblastic anemia. This can prevent appropriate treatment with vitamin B12 and result in neurological damage, such as subacute combined degeneration of the spinal cord.
- Patients with Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

4.4 Special warnings and precautions for use

- Folic acid and vitamin B12 after coronary stenting may increase restenosis rates.
- Folic acid may exacerbate seizures in patients with epilepsy in doses larger than 1000 µg daily.

4.5 Interaction with other medicines and other forms of interaction

- Requirements for folic acid may be increased in patients taking anticonvulsants, however, the concurrent use of folic acid may antagonize the effects of anticonvulsants, which may increase the anticonvulsant dose required. Patients should be monitored closely for increased seizure activity.
- High doses of folic acid might contribute to capecitabine toxicity.
- High doses of folic acid may increase toxicity of fluorouracil.
- Pyridoxine reduces the effects of levodopa and reduces the activity of altretamine.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

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 B-COMPLEX does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Frequency unknown: gastrointestinal disturbances.

Immune System

Frequency unknown: hypersensitivity reactions.

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

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Folic acid contributes to maternal tissue growth during pregnancy, helps to form red blood cells, and helps to reduce the risk of neural tube defects when taking daily prior to becoming pregnant and during early pregnancy.

B-vitamins contribute to the normal function of the nervous system, the psychological function, the immune system, and contributes to the reduction of tiredness and fatigue.

5.2 Pharmacokinetic properties

Thiamine (vitamin B1) is well absorbed in small amounts from the gastrointestinal tract. It is widely distributed to most body tissues and appears in breast milk. Excess amounts are excreted in the urine unchanged or as metabolites.

Riboflavin (vitamin B2) is readily absorbed from the gastrointestinal tract. Although widely distributed to body tissues, little is stored in the body. Riboflavin is excreted in urine, partly as metabolites. Riboflavin crosses the placenta and is distributed into breast milk.

Nicotinamide (vitamin B3) is readily absorbed from the gastrointestinal tract and widely distributed in body tissues. Nicotinic acid appears in breast milk.

Pantothenic acid (vitamin B5) is readily absorbed from the gastrointestinal tract after oral doses. It is widely distributed in the body tissues and appears in breast milk. About 70% of pantothenic acid is excreted unchanged in the urine and about 30% in the faeces.

Pyridoxine (vitamin B6) is readily absorbed from the gastrointestinal tract and is converted to the active forms: pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is oxidation to 4-pyridoxic acid and other inactive metabolites which are excreted in the urine. Pyridoxal crosses the placenta and is distributed into breast milk.

Folic acid is readily absorbed from the gastrointestinal tract, mainly from the duodenum and jejunum. After absorption, folic acid is reduced to tetrahydrofolate and then enters a methylation cycle where it is then converted to L-methylfolate. Folic acid is excreted mainly in the urine, but is also found in the faeces. Folic acid is removed by haemodialysis. Folic acid is distributed in breast milk.

Vitamin B12 substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion. Vitamin B12 is extensively bound to specific plasma proteins called transcobalamins. Vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling. A small part of vitamin B12 is excreted in urine. Vitamin B12 diffuses across the placenta and also appears in breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dicalcium phosphate, microcrystalline cellulose, stearic acid and white coating.

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

60 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**

LOCAL HEALTH B-COMPLEX (tablets)

Each tablet contains:

Nicotinamide (Vitamin B3)	16 mg
Pantothenic Acid (Vitamin B5)	5 mg
Pyridoxine (Vitamin B6)	1,7 mg
Riboflavin (Vitamin B2)	1,3 mg
Thiamine (Vitamin B1)	1,2 mg
Folic Acid (Vitamin B9)	400 µg
Biotin (Vitamin B7)	30 µg
Cyanocobalamin (Vitamin B12)	2,4 µg

Sugar free

Complementary Medicine: Vitamins (Health Supplement)

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

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH B-COMPLEX 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 B-COMPLEX is and what it is used for.
2. What you need to know before you use LOCAL HEALTH B-COMPLEX.
3. How to use LOCAL HEALTH B-COMPLEX.
4. Possible side effects.
5. How to store LOCAL HEALTH B-COMPLEX.
6. Contents of the pack and other information.

1. What LOCAL HEALTH B-COMPLEX is and what it is used for

LOCAL HEALTH B-COMPLEX contains a combination of B-vitamins which support the normal functioning of the nervous system, contribute to the reduction of tiredness and fatigue, supports energy-yielding metabolism and which play a role in the maintenance of good health.

2. What you need to know before you use LOCAL HEALTH B-COMPLEX

Do not use LOCAL HEALTH B-COMPLEX:

- If you are allergic or sensitive to any of the ingredients listed in section 6.
- If you are hypersensitive or allergic to cobalamin or cobalt.
- If you have a suspected but undiagnosed vitamin B12 deficiency.
- If you have Leber's disease or tobacco amblyopia.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH B-COMPLEX, especially if you have a medical condition. Use LOCAL HEALTH B-COMPLEX with caution and consult a healthcare practitioner before use:

- If you are receiving a coronary stent.
- If you suffer from epilepsy.

Children and adolescents

LOCAL HEALTH B-COMPLEX is not recommended for children below the age of 14 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH B-COMPLEX

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 B-COMPLEX may interact with the following medications: anticonvulsants, capecitabine, fluorouracil, levodopa, alprazolam.

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 B-COMPLEX.

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 B-COMPLEX does not adversely affect their performance.

3. How to use LOCAL HEALTH B-COMPLEX

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH B-COMPLEX 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 14 years and older:

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

4. Possible side effects

LOCAL HEALTH B-COMPLEX can have side effects. Not all side effects reported for LOCAL HEALTH B-COMPLEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH B-COMPLEX, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH B-COMPLEX and tell your doctor or pharmacist immediately, or go to 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 B-COMPLEX. You may need urgent medical attention or hospitalisation.

- **Frequency unknown:** hypersensitivity reactions, gastrointestinal disturbances.

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 B-COMPLEX.

5. How to store LOCAL HEALTH B-COMPLEX

- 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 B-COMPLEX to your pharmacist.
- Do not dispose of unused LOCAL HEALTH B-COMPLEX in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH B-COMPLEX contains

Each tablet contains:

Nicotinamide (Vitamin B3)	16 mg
Pantothenic Acid (Vitamin B5)	5 mg
Pyridoxine (Vitamin B6)	1,7 mg
Riboflavin (Vitamin B2)	1,3 mg
Thiamine (Vitamin B1)	1,2 mg
Folic Acid (Vitamin B9)	400 µg
Biotin (Vitamin B7)	30 µg
Cyanocobalamin (Vitamin B12)	2,4 µg

Other ingredients: dicalcium phosphate, microcrystalline cellulose, stearic acid and white coating.

Sugar free

Presentation and identification of LOCAL HEALTH B-COMPLEX

60 round, 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@cjdsa.com; 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.

**PASIENTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

LOCAL HEALTH B-COMPLEX (tablette)

Elke tablet bevat:

Nikotinamied (Vitamiën B3)	16 mg
Pantoteensuur (Vitamiën B5)	5 mg
Piridoksien (Vitamiën B6)	1,7 mg
Riboflaviën (Vitamiën B2)	1,3 mg
Tiamien (Vitamiën B1)	1,2 mg
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Biotien (Vitamiën B7)	30 µg
Sianokobalamin (Vitamiën B12)	2,4 µg

Suikervry

Komplementêre Medisyne: Vitamene (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 B-COMPLEX is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH B-COMPLEX 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 B-COMPLEX 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 B-COMPLEX is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH B-COMPLEX gebruik.
3. Hoe om LOCAL HEALTH B-COMPLEX te gebruik.
4. Moontlike newe-effekte.
5. Berging van LOCAL HEALTH B-COMPLEX.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH B-COMPLEX is en waarvoor dit gebruik word

LOCAL HEALTH B-COMPLEX bevat 'n kombinasie van B-vitamene wat die normale funksionering van die senuweestelsel ondersteun, bydra tot die vermindering van tansheid en moegheid, die energie-gewende metaboliese ondersteun, en 'n rol speel in die handhaving van goeie gesondheid.

2. Wat u moet weet voordat u LOCAL HEALTH B-COMPLEX gebruik

Moet nie LOCAL HEALTH B-COMPLEX neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u hipersensitief of allergies is vir kobalamin of kobalt.
- Indien u 'n vermoede maar ongediagnoseerde vitamien-B12 tekort het.
- Indien u Leber se siekte of tabak amblyopie het.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH B-COMPLEX gebruik, veral as u 'n mediese toestand het. Gebruik LOCAL HEALTH B-COMPLEX met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u 'n koronêre stent ontvang.
- Indien u aan epilepsie ly.

Kinders en adolessente

LOCAL HEALTH B-COMPLEX word nie aanbeveel vir kinders jonger as 14 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH B-COMPLEX 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 B-COMPLEX kan interaksie hê met die volgende medisyne: antikonvulsante, capecitabine, fluorouracil, levodopa, altramien.

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 B-COMPLEX gebruik.

Bestuur en die gebruik van masjinerie

Gen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH B-COMPLEX nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH B-COMPLEX te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH B-COMPLEX presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 14 jaar en ouer:

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

4. Moontlike newe-effekte

LOCAL HEALTH B-COMPLEX kan newe-effekte hê. Nie alle newe-effekte vir LOCAL HEALTH B-COMPLEX is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH B-COMPLEX, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH B-COMPLEX 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, gejuuk, of floutes. Hierdie is baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH B-COMPLEX gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Dikwelsheid onbekend:** hipersensitiewe reaksies, gastrointestinale verstoringe.

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

Rapportering van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. U kan ook newe-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 newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH B-COMPLEX.

5. Berging van LOCAL HEALTH B-COMPLEX

- 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 B-COMPLEX na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH B-COMPLEX in afvoertipes of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH B-COMPLEX bevat

Elke tablet bevat:

Nikotinamied (Vitamiën B3)	16 mg
Pantoteensuur (Vitamiën B5)	5 mg
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Foliensuur (Vitamiën B9)	400 µg
Biotien (Vitamiën B7)	30 µg
Sianokobalamin (Vitamiën B12)	2,4 µg

Ander bestanddele: di-kalsiumfosfaat, mikrokristallyne sellulose, steariensuur en wit deklaag.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH B-COMPLEX

60 ronde, 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 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.