

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 B12 & FOLIC ACID sublingual tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Folic Acid	500 µg
Cyanocobalamin (Vitamin B12)	25 µg

Contains sugar: 145 mg sorbitol per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Small, oval, light yellow sublingual tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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. Vitamin B12 contributes to the normal function of the nervous system, the psychological function, the immune system, and contributes to the reduction of tiredness and fatigue.

4.2 Posology and method of administration

Adults and children 14 years and older: one (1) tablet daily, place under the tongue and allow to fully dissolve.

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.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of LOCAL HEALTH B12 & FOLIC ACID in 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 B12 & FOLIC ACID 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.

Vitamin B12 contributes 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

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, yellow colouring, sorbitol, 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

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**

SO
LOCAL HEALTH B12 & FOLIC ACID (sublingual tablets)

Each tablet contains:

Folic Acid	500 µg
Cyanocobalamin (Vitamin B12)	25 µg

Contains sugar: 145 mg sorbitol per tablet.

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 B12 & FOLIC ACID is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH B12 & FOLIC ACID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID is and what it is used for.
2. What you need to know before you use LOCAL HEALTH B12 & FOLIC ACID.
3. How to use LOCAL HEALTH B12 & FOLIC ACID.
4. Possible side effects.
5. How to store LOCAL HEALTH B12 & FOLIC ACID.
6. Contents of the pack and other information.

1. What LOCAL HEALTH B12 & FOLIC ACID is and what it is used for

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. Vitamin B12 contributes to the normal function of the nervous system, the psychological function, the immune system, and contributes to the reduction of tiredness and fatigue.

2. What you need to know before you use LOCAL HEALTH B12 & FOLIC ACID

Do not use LOCAL HEALTH B12 & FOLIC ACID:

- 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 B12 & FOLIC ACID, especially if you have a medical condition.

Use LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID is not recommended for children below the age of 14 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH B12 & FOLIC ACID

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 B12 & FOLIC ACID may interact with the following medications: anticonvulsants, capecitabine, fluorouracil.

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 B12 & FOLIC ACID.

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 B12 & FOLIC ACID does not adversely affect their performance.

3. How to use LOCAL HEALTH B12 & FOLIC ACID

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH B12 & FOLIC ACID 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. Place under the tongue and allow to fully dissolve.

4. Possible side effects

LOCAL HEALTH B12 & FOLIC ACID can have side effects. Not all side effects reported for LOCAL HEALTH B12 & FOLIC ACID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH B12 & FOLIC ACID, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID. 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 B12 & FOLIC ACID.

5. How to store LOCAL HEALTH B12 & FOLIC ACID

- 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 B12 & FOLIC ACID to your pharmacist.
- Do not dispose of unused LOCAL HEALTH B12 & FOLIC ACID in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH B12 & FOLIC ACID contains

Each tablet contains:

Folic Acid	500 µg
Cyanocobalamin (Vitamin B12)	25 µg

Other ingredients: dicalcium phosphate, yellow colouring, sorbitol, magnesium stearate.

Contains sugar: 145 mg sorbitol per tablet.

Presentation and identification of LOCAL HEALTH B12 & FOLIC ACID

60 small, oval, light yellow 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.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

SO
LOCAL HEALTH B12 & FOLIC ACID (sublinguale tablette)

Elke tablet bevat:

Foliensuur	500 µg
Sianokobalamien (Vitamiën B12)	25 µg

Bevat suiker: 145 mg sorbitol per tablet.

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 B12 & FOLIC ACID is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID 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 B12 & FOLIC ACID is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH B12 & FOLIC ACID gebruik.
3. Hoe om LOCAL HEALTH B12 & FOLIC ACID te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH B12 & FOLIC ACID.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH B12 & FOLIC ACID is en waarvoor dit gebruik word

Foliensuur dra by tot die groei van moederweefsel tydens swangerskap, help om rooibloedselle te vorm en help om die risiko van neurale buisdefekte te verminder wanneer u dit daagliks neem voordat u swanger raak en tydens vroeë swangerskap. Vitamiën B12 dra by tot die normale funksie van die senuweestelsel, die psilogiese funksie, die immuunstelsel, en dra by tot die vermindering van tamheid en moegheid.

2. Wat u moet weet voordat u LOCAL HEALTH B12 & FOLIC ACID gebruik

Moet nie LOCAL HEALTH B12 & FOLIC ACID neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u hipersensitief of allergies is vir kobalamien of kobalt.
- Indien u 'n vermeende 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 B12 & FOLIC ACID gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH B12 & FOLIC ACID met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

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

Kinders en adolessente

LOCAL HEALTH B12 & FOLIC ACID word nie aanbeveel vir kinders jonger as 14 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID kan interaksie hê met die volgende medisyne: antikonvulsante, capecitabine, fluorouracil.

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 B12 & FOLIC ACID 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. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH B12 & FOLIC ACID nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH B12 & FOLIC ACID 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 B12 & FOLIC ACID 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 daagliks, of soos aanbeveel deur 'n gesondheidsorgpraktisyn. Plaas onder die tong en laat dit heeltemal oplos.

4. Moontlike nuwe-effekte

LOCAL HEALTH B12 & FOLIC ACID kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH B12 & FOLIC ACID is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH B12 & FOLIC ACID, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH B12 & FOLIC ACID en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevallen 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 nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH B12 & FOLIC ACID gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Dikwelsheid onbekend:** hipersensitiwiteitsreaksies, gastrointestinale verstourings.

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 B12 & FOLIC ACID.

5. Berging van LOCAL HEALTH B12 & FOLIC ACID

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUIE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH B12 & FOLIC ACID na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH B12 & FOLIC ACID in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH B12 & FOLIC ACID bevat

Elke tablet bevat:	
Foliensuur	500 µg
Sianokobalamien (Vitamiën B12)	25 µg

Ander bestanddele: dikalsiumfosfaat, geel kleurstof, sorbitol, magnesiumstearaat.

Bevat suiker: 145 mg sorbitol per tablet.

Aanbieding en identifikasie van LOCAL HEALTH B12 & FOLIC ACID

60 klein, ovaal, liggeel tablette verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorgly: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.