PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.
Discipline: Health Supplement
33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

FOLAPRO® PLUS, 120 Tablets

COMPOSITION

Each one (1) tablet of FOLAPRO® PLUS contain the following actives:

Folate (as Calcium-L-methylfolate)	400 µg
Vitamin B12 (as Methylcobalamin)	25 µg

Inactive Ingredients: : Common bamboo extract (Bambusa vulgaris Schrad.), dicalcium phosphate, magnesium carbonate, microcrystalline cellulose, silicon dioxide, stearic acid.

This product is suitable for Vegetarians gluten free, non-GMO and Sugar Free.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

FOLAPRO® PLUS features the methylated forms of folate and vitamin B12 that may assist many body processes and are especially important during pregnancy.

Ingredients	Uses for ingredient
Folate (as Calcium-L-methylfolate)	Folate has many functions in the body: Helps tissues grow and cells work. Works with vitamin B12 and vitamin C to help the body break down, use, and create new proteins. Helps form red blood cells (helps prevent anaemia)
Vitamin B12 (as Methylcobalamin)	Vitamin B12 has many roles in your body. It supports the function of your nerve cells and is needed for red blood cell formation and DNA synthesis.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **FOLAPRO® PLUS** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Procedures to widen narrowed arteries (angioplasty), Cancer, Seizure disorder, Vitamin B12 deficiency Taking folic acid supplements might improve certain lab tests in people with low vitamin B12 levels (This may make it seem like vitamin B12 deficiency is improved when it isn't. If left untreated, this could cause permanent nerve damage). If you are taking the following medication, please consult with your healthcare professional before taking: Fosphenytoin (Cerebyx), Phenobarbital (Luminal), Phenytoin (Dilantin), Primidone used for seizures, Pyrimethamine used to treat parasite infections, 5-Fluorouracil. If any of the following happens, stop using **FOLAPRO® PLUS** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;

These are all very serious effects. If you have them, you may have had a serious reaction to **FOLAPRO® PLUS.** You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Diarrhoea, Fatigue, Headache, Nausea

These are all very serious effects. If you have them, you may have had a serious reaction to **FOLAPRO® PLUS**. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) tablet daily or as directed by your healthcare Practitioner.

Do no take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.
Protect from direct sunlight and heat.
Store in the original bottle.
Keep the bottle tightly closed.
Replace the protective cap after each use.
Do not use after the expiry date stated on the bottle.
Do not use **FOLAPRO® PLUS** if you notice visible signs of deterioration.

IDENTIFICATION

Uncoated, round white tablet..

PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

This medicine has not been evaluated by SAHPRA for quality, safety, or intended use.

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:
Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146
Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

Document reference: FOLA.PI.V1 12-24

PROFESSIONELE INLIGTINGSBLAD

SKEDULERINGSTATUS: S0.
Kategorie D: Komplementêre medisyne.
Dissipline: Gesondheidsaanvulling
34.12 Meervoudige Bestandeel Formulasie

HANDELSNAAM EN DOSEERVORM**,**

FOLAPRO® PLUS, 120 Tablette

SAMESTELING

Elke (1) tablet FOLAPRO® PLUS bevat die volgende aktiewe stowwe:

Folaat (as kalsium-L-metielfolaat)	400 µg
Vitamien B12 (as metielkobalamien)	25 µg

Onaktiewe bestanddele: Algemene bamboesekstrak (Bambusa vulgaris Schrad.), Dikalsiumfosfaat, magnesiumkarbonaat, mikrokristallyne sellulose, silikondioksied, steariensuur.
Hierdie produk is geskik vir vegetariërs glutenvry, nie-GGO en suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING
FOLAPRO® PLUS bevat die gemetileerde vorme van folaat en vitamien B12 wat baie liggaamsprosesse kan help en veral belangrik tydens swangerskap.

Bestanddele	Gebruike vir bestanddeel
Folaat (as kalsium-L-metielfolaat)	Folaat het baie funksies in die liggaam: Help weefsels groei en selle werk. Werk saam met vitamien B12 en vitamien C om die liggaam te help om proteïene af te breek, te gebruik en te skep. Help om rooibloedselle te vorm (help bloedarmoede voorkom)
Vitamien B12 (as metielkobalamien)	Vitamien B12 het baie rolle in jou liggaam. Dit ondersteun die funksie van jou senuweeselle en is nodig vir rooibloedselvorming en DNA-sintese.

KONTRA-INDIKASIES:
As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisynr te raadpleeg nie. Moenie **FOLAPRO® PLUS** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisynr gaan praat voordat jy hierdie aanvulling neem.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS
Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik Prosedures om vernoude are (angioplastiek), kanker, beslagleggingsversteuring, vitamien B12-tekort te verbreed Die neem van foliensuuraanvullings kan sekere laboratoriumtoetse verbeter by mense met lae vitamien B12-vlakke (Dit kan dit laat lyk asof vitamien B12-tekort verbeter word as dit nie is nie As dit nie behandel word nie, kan dit permanente senuweeskade veroorsaak). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Fosfenytoin (Cerebyx), Fenobarbital (Luminal), Fenitoïen (Dilantin), Primidone wat gebruik word vir aanvalle, Pyrimethamine wat gebruik word om parasietversteurings te behandel, 5-Fluorouracil. As enige van die volgende gebeur, hou op om **FOLAPRO® PLUS** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling.;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **FOLAPRO® PLUS** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.
Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Diarree, moegheid, hoofpyn, naarheid..

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **FOLAPRO® PLUS** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.
Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind.
Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.
• Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
• Moenie medisyne met enige ander persoon deel nie.
• Vra jou apteker of jy meer inligting of advies benodig.
• Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.
MOENIE HIERDIE PRODUK GEBRUIK NIE:
• As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
• Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES
Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK
Volwasse Neem een (1) tablet daagliks of soos voorgeskryf deur jou gesondheidsorgpraktisyn.
Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE
Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie aanvulling, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien newe-effekte.
Behandeling:
Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE
Hou dig toegemaak op 'n koel, droë plek, onder 25 °C.
Beskerm teen direkte sonlig en hitte.
Bêre n die oorspronklike bottel.
Hou die bottel styf toe.
Vervang die beskermende dop na elke gebruik.
Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.
Moenie **FOLAPRO® PLUS** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE
Onbedekte, ronde wit tablet.

AANBIEDING
'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER
Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT
Versprei deur:
Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension,
Sandton, 2146,
Tel: 011- 802-8101

DATUM VAN PUBLIKASIE
Om deur die regulerende owerheid toegeken te word.