PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0.
Category D: Complementary medicine.
Discipline: Health Supplement
33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

FOLAPRO® PLUS, 120 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **FOLAPRO® PLUS is** available without a doctor's prescription.
- Nevertheless, you still need to use **FOLAPRO® PLUS** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **FOLAPRO® PLUS** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

WHAT FOLAPRO® PLUS CONTAINS

Each one (1) tablet of FOLAPRO® PLUS contains 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.

WHAT FOLAPRO® PLUS IS AND WHAT IT IS USED FOR

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

BEFORE YOU TAKE FOLAPRO® PLUS

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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.

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

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **FOLAPRO® PLUS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **FOLAPRO® PLUS** may affect you.

TAKING OTHER MEDICINES WITH FOLAPRO® PLUS

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner.

HOW TO TAKE FOLAPRO® PLUS

Do not share medicines prescribed for you with any other person. Always take **FOLAPRO® PLUS** exactly as described in this leaflet, or as your doctor, healthcare practitioner has instructed you. You should check with your doctor, pharmacist or healthcare practitioner if you are unsure.

Directions for use:

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

Do no take more than the recommended dose.

IF YOU TAKE MORE FOLAPRO® PLUS THAN YOU SHOULD

In the event of overdosage, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE FOLAPRO® PLUS

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

POSSIBLE SIDE EFFECTS

FOLAPRO® PLUS may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **FOLAPRO® PLUS** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **FOLAPRO® PLUS.**

STORAGE AND DISPOSING OF FOLAPRO® PLUS

Store all medicines out of the reach of children.
Store in a cool, dark place, below 25 °C.
Protect from direct sunlight and heat.
Store in the original packaging.
Do not use after the expiry date stated on the bottle.
Do not use **FOLAPRO® PLUS** if you notice visible signs of deterioration.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF FOLAPRO® PLUS

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

IDENTIFICATION OF FOLAPRO® PLUS

Uncoated, round white tablet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

19 November 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:
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PASIËNT INLIGTINGSBLAD

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

HANDELSNAAM EN DOSEERVORM**,**

FOLAPRO® PLUS, 120 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U

- **FOLAPRO® PLUS** is beskikbaar sonder doktersvoorskrif**.**
- U moet steeds **FOLAPRO® PLUS** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **FOLAPRO® PLUS** met enige ander persoon deel nie**.**
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **FOLAPRO® PLUS** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **FOLAPRO® PLUS** neem**.**
- Hoe om **FOLAPRO® PLUS** te neem.
- Moontlike newe-effekte.
- Hoe om **FOLAPRO® PLUS** te bêre.
- Inhoud van die pak en ander inligting

WATTER FOLAPRO® PLUS BEVAT

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

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.

WAT IS FOLAPRO® PLUS KAPSULES EN WAARVOOR WORD DIT GEBRUIK

FOLAPRO® PLUS bevat die gemetileerde vorme van folaat en vitamien B12 wat baie liggaamsprosesse kan help en veral
Belangrik tydens swangerskap.

VOORDAT JY FOLAPRO® PLUS NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn 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 gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

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

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is vasgestel. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

BESTUUR EN GEBRUIK VAN MASJIENE

Dit is nie altyd moontlik om te voorspel in watter mate **FOLAPRO® PLUS** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **FOLAPRO® PLUS** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET FOLAPRO® PLUS

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne ´n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

HOE OM FOLAPRO® PLUS TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **FOLAPRO® PLUS** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.
Aanwysings vir gebruik:
Volwasse: Neem een (1) tablet daagliks of soos voorgeskryf deur jou gesondheidsorgpraktisyn.
Moenie meer as die aanbevole dosis neem nie.

AS JY MEER FOLAPRO® PLUS NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGEET OM FOLAPRO® PLUS TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

MOONTLIKE NEWE-EFFEKTE

FOLAPRO® PLUS kan newe-effekte hê.
Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: angioplastie, 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 wanneer 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 parasietinfeksies 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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.
Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- Diarree, moegheid, hoofpyn, naarheid..

Nie alle newe-effekte en interaksies wat vir **FOLAPRO® PLUS** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, 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.

AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:
https://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 **FOLAPRO® PLUS.**

HOE OM FOLAPRO® PLUS TE BERÊ

Hou buite bereik van kinders.
Hou dig toegemaak op 'n koel, droë plek, onder 25 °C.
Beskerm teen direkte sonlig en hitte.
Bêre in die oorspronklike verpakking.
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.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN FOLAPRO® PLUS

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

IDENTIFIKASIE VAN FOLAPRO® PLUS

Onbedekte, ronde wit tablet.

REGISTRATION NOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

NAAM EN ADRES VAN REGISTRASIEHOUER

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