

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.
Discipline: Health Supplement
34.12 Multiple substance formulation



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

INTRINSI B12-FOLATE™, 60 Tablets

COMPOSITION

Each one (1) tablet of INTRINSI B12-FOLATE™ contains the following actives:

Intrinsic Factor	20 mg
Folate (as Calcium L-5-methyltetrahydrofolate)	500 µg
Vitamin B12 (as Methylcobalamin)	100 µg

Inactive Ingredients: Dicalcium phosphate, magnesium carbonate, magnesium stearate, microcrystalline cellulose, silicon dioxide.

This product is suitable for non-GMO, gluten free and dairy free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

INTRINSI B12-FOLATE™ features the active forms of vitamin B12 and folate with intrinsic factor for enhanced absorption and utilisation. These nutrients help promote nervous system function and cardiovascular health.

Ingredients	Uses for ingredient
Intrinsic Factor	It is a protein secreted by the cells lining the stomach and it is essential for the absorption of vitamin B12 in the intestines. Our immune system operates as a finely orchestrated mechanism and cannot function effectively, without intrinsic factor. ¹
Folate (as Calcium L-5-methyltetrahydrofolate)	Folate is the natural form of vitamin B9 that the body needs to maintain its genetic building blocks, DNA and RNA. ² In addition, it supports healthy cell division. ³
Vitamin B12 (as Methylcobalamin)	Methylcobalamin is a naturally occurring form of vitamin B12. Vitamin B12 is important for the brain and nerves, and to produce red blood cells. ⁴ Vitamin B12 is required for the development, myelination, and function of the central nervous system; healthy red blood cell formation ⁵ ; and DNA synthesis. Vitamin B12 functions as a cofactor for two enzymes, methionine synthase and L-methylmalonyl-CoA mutase. ⁶

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **INTRINSI B12-FOLATE™** 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. **Laboratory tests:** This medication may interfere with certain lab tests (such as blood tests for other types of anaemia), possibly causing false test results. Make sure lab personnel and all your doctors know you use this medicine.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Angioplasty, Seizure disorder, Stomach problems, Low potassium levels (hypokalemia), Crohns disease, Post surgical stent placement. If you are taking the following medication, please consult with your healthcare professional before taking: oral diabetes medicine, medicines that reduce stomach acid. Avoid drinking large amounts of alcohol. Heavy drinking can make it harder for your body to absorb methylcobalamin. If any of the following happens, stop using **INTRINSI B12-FOLATE™** 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;

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These are all very serious effects. If you have them, you may have had a serious reaction to **INTRINSI B12-FOLATE™**. 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):

- Stomach discomfort.

These are all very serious effects. If you have them, you may have had a serious reaction to **INTRINSI B12-FOLATE™**. 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

Adult: Take 1 tablet daily or as directed by your healthcare professional.

Do not 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 **INTRINSI B12-FOLATE™** if you notice visible signs of deterioration.

IDENTIFICATION

Uncoated, round light pink tablet.

PRESENTATION

A white 175 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.

¹ <https://www.drathresearch.org/latest-news/item/49-improve-your-immunity-with-intrinsic-factor>

² <https://www.verywellhealth.com/what-is-folate-1763888>

³ National Institutes of Health: Office of Dietary Supplements. Folate: Fact sheet for consumers.

⁴ <https://www.drugs.com/mtm/methylcobalamin-vitamin-b12.html>

⁵ <https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/#en5>

⁶ Stabler SP. Vitamin B12. In: Marriot BP, Birt DF, Stallings VA, Yates AA, eds. Present Knowledge in Nutrition. 11th ed. Washington, DC: Elsevier; 2020:257-71.

PROFESIONELE INLIGTING

SKEDULERINGSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Disipliene: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

INTRINSI B12-FOLATE™, 60 tablette

SAMESTELING

Elke (1) tablet INTRINSI B12-FOLATE™ bevat die volgende aktiewe bestanddele:

Intrinsieke faktor	20 mg
Folaat (as kalsium L-5-metieltetrahydrofolaat)	500 µg
Vitamiën B12 (as metielkobalamien)	100 µg

Onktiewe bestanddele: Dikalsiumfosfaat, magnesiumkarbonaat, magnesiumstearaat, mikrokrystallyn-sellulose, silikondioksied.

Hierdie produk is geskik vir nie-GGO, glutenvry en suiwelvry (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

INTRINSI B12-FOLATE™ beskik oor die aktiewe vorms van vitamien B12 en folaat saam met intrinsieke faktor om absorpsie en benutting te verbeter. Hierdie nutriente help om senuweestelsel funksie en kardiovaskulêre gesondheid te bevorder.

Bestanddele	Gebruike vir bestanddeel
Intrinsieke faktor	Dit is 'n proteïen wat afgeskei word deur die selle wat die maag beklee, en dit is noodsaaklik vir die opname van vitamien B12 in die ingewande. Ons immuunstelsel funksioneer as 'n fyn georkestreerde meganisme en kan nie effektië funksioneer sonder intrinsieke faktor nie. ⁷
Folaat (as kalsium L-5-metieltetrahydrofolaat)	Folaat is die natuurlike vorm van vitamien B9 wat die liggaam nodig het om sy genetiese boustone, DNA en RNA te handhaaf. ⁸ Daarbenewens ondersteun dit gesonde selding. ⁹
Vitamiën B12 (as metielkobalamien)	Metielkobalamien is 'n natuurlike vorm van vitamien B12. Vitamiën B12 is belangrik vir die brein en senuwees, en om rooibloedselle te produseer. ¹⁰ Vitamiën B12 is nodig vir die ontwikkeling, myelinisering en funksie van die sentrale senuweestelsel; gesonde rooibloedselvorming ¹¹ ; en DNA-sintese. Vitamiën B12 funksioneer as 'n kofaktor vir twee ensieme, metionien sintase en L-metilmaloniël-CoA-mutase. ¹²

KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **INTRINSI B12-FOLATE™** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy koel/die het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. Laboratoriumtoets: Hierdie medisyne kan inmeng met sekere laboratoriumtoetses (soos bloedoetses vir ander soorte bloedmoeie), wat moontlik vals toetsresultate kan veroorsaak. Maak seker dat laboratoriumpersoneel en al jou dokters weet dat jy hierdie medisyne gebruik.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Angioplastie, Stuipeversteuring, Maagprobleme, Lae kaliumvlakke (hipokalemie), Chrohns-siekte, Postchirurgiese stentplasing. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: orale diabetes medisyne, medisyne wat maagsuur vermind. Vermoed dat jy drink van groot hoeveelhede alkohol. Swaar drink kan dit moeiliker maak vir jou liggaam om metielkobalamien te absorbeer. As enige van die volgende gebeur, hou op om **INTRINSI B12-FOLATE™** 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;

Document Reference: IBF.PI.V01 10-24

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **INTRINSI B12-FOLATE™** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nowe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Maag ongemak.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **INTRINSI B12-FOLATE™** 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 vouiljet aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie vouiljet. 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.

INTERAKSIE

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**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem 1 tablet daaglik 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 terwyl jy aan hierdie produk blootgestel word, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad.

BEKENDE SIMPTOME VAN OORDOERSING 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 in 'n koel, donker plek, onder 25 °C.

Besker teen direkte sonlig en hitte.

Bêre in 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 **INTRINSI B12-FOLATE™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE - Onbedekte, ronde ligpignt tablet.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om deur SAHPRA toegeken te word by registrasie.

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

NAAM EN BESIGHEIDSDRES 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.

⁷ <https://www.drathresearch.org/latest-news/item/49-immune-your-immunity-with-intrinsic-factor>

⁸ <https://www.verywellhealth.com/what-is-folate-1763888>

⁹ Nasionale Instituut vir Gesondheid: Kantoer van Dieetaanvullings. Folaat: Feiteblad vir verbruikers.

¹⁰ <https://www.drugs.com/mtm/methylcobalamin-vitamin-b12.html>

¹¹ <https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/#en5>

¹² Stabler SP. Vitamiën B12. In: Marriott BP, Birt DF, Stallings VA, Yates AA, reds. Huidige kennis in voeding. 11de uitgawe. Washington, DC: Elsevier; 2020:257-71.

