

PATIENT INFORMATION LEAFLET

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

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

- **INTRINSI B12-FOLATE™** is available without a doctor's prescription.
- Nevertheless, you still need to use **INTRINSI B12-FOLATE™** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **INTRINSI B12-FOLATE™** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **INTRINSI B12-FOLATE™** is and what it is used for.
- What you need to know before you take **INTRINSI B12-FOLATE™**.
- How to take **INTRINSI B12-FOLATE™**.
- Possible side effects.
- How to store **INTRINSI B12-FOLATE™**.
- Contents of the pack and other information.

WHAT INTRINSI B12-FOLATE™ CONTAINS

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)

WHAT INTRINSI B12-FOLATE™ ARE USED FOR

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.

BEFORE YOU TAKE INTRINSI B12-FOLATE™

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 anemia), possibly causing false test results. Make sure lab personnel and all your doctors know you use this medicine. This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.

PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has been established, consult with your healthcare professional before use. 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 **INTRINSI B12-FOLATE™** 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 coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until you are aware of the measure to which **INTRINSI B12-FOLATE™** may affect you.

TAKING OTHER MEDICINES WITH INTRINSI B12-FOLATE™

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 professional.

HOW TO TAKE INTRINSI B12-FOLATE™

Do not share medicines prescribed for you with any other person. Always take **INTRINSI B12-FOLATE™** exactly as described in this leaflet, or as your doctor, your healthcare professional has directed you. You should check with your doctor, pharmacist or healthcare professional if you are unsure.

Directions for use:

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

Do not take more than the recommended dose.

IF YOU TAKE MORE INTRINSI B12-FOLATE™ THAN YOU SHOULD

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



IF YOU FORGET TO TAKE INTRINSI B12-FOLATE™

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

POSSIBLE SIDE EFFECTS

INTRINSI B12-FOLATE™ may have side effects.

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.

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.

Not all side effects and interactions reported for **INTRINSI B12-FOLATE™** 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 **INTRINSI B12-FOLATE™**.

STORAGE AND DISPOSING OF INTRINSI B12-FOLATE™

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 **INTRINSI B12-FOLATE™** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF INTRINSI B12-FOLATE™

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

IDENTIFICATION OF INTRINSI B12-FOLATE™

Uncoated, round light pink 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

11 October 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
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Sandton, 2146
Tel: 011-802-8101



PASÏENT INLIGTINGSBLAD

SKEDULERINGSSTATUS ^[50]

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestandeel Formulasie

HANDELSNAAM EN DOSEERVORM,

INTRINSI B12-FOLATE™, 60 tablette

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

- **INTRINSI B12-FOLATE™** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **INTRINSI B12-FOLATE™** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **INTRINSI B12-FOLATE™** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisy van jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **INTRINSI B12-FOLATE™** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **INTRINSI B12-FOLATE™** neem.
- Hoe om **INTRINSI B12-FOLATE™** te neem.
- Moontlike nuwe-effekte.
- Hoe om **INTRINSI B12-FOLATE™** te bêre.
- Inhoud van die pak en ander inligting.

WAT INTRINSI B12-FOLATE™ BEVAT

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

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

Onaktiewe bestanddele: Dikalsiumfosfaat, magnesiumkarbonaat, magnesiumstearaat, mikrokristallyn-sellulose, silikondioksied.

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

WAT IS INTRINSI B12-FOLATE™ EN WAARVOOR WORD DIT GEBRUIK

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

VOORDAT JY INTRINSI B12-FOLATE™ NEEM

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 allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn praat voordat jy hierdie aanvulling neem. **Laboratoriumtoets:** Hierdie medisyne kan inmeng met sekere laboratoriumtoetses (soos bloedtoets vir ander soorte bloedarmoede), wat moontlik vals toetsresultate kan veroorsaak. Maak seker dat laboratoriumpersoneel en al jou dokters weet dat jy hierdie medisyne gebruik.

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

SWANGERSKAP EN BORSWOEDING

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. 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 MASHIENE

Dit is nie altyd moontlik om te voorspel in watter mate **INTRINSI B12-FOLATE™** 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, vr, vlieg, seil, bedryfsmasjien/toerusting, totdat jy bewus is van die mate waartoe **INTRINSI B12-FOLATE™** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET INTRINSI B12-FOLATE™

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 INTRINSI B12-FOLATE™ TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **INTRINSI B12-FOLATE™** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:

Volwasse nes: Neem 1 tablet daaglik of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER INTRINSI B12-FOLATE™ NEEM AS WAT JY MOET

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

AS JY VERGEET OM INTRINSI B12-FOLATE™ TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

INTRINSI B12-FOLATE™ kan nuwe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Angioplastie, Stuipeversterking, 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 verminder. Vermoed die 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 ongevallenafdeling 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 **INTRINSI B12-FOLATE™** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- Maag ongemak.

Nie alle nuwe-effekte en interaksies wat vir **INTRINSI B12-FOLATE™** 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 nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **INTRINSI B12-FOLATE™**.

HOE OM INTRINSI B12-FOLATE™ TE BÊRÊ

Bêre alle medisyne buite bereik van kinders.

Hou in 'n koel, donker plek, onder 25 °C.

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

Moenie ongebruikte medisyne in dreine of rioelstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN INTRINSI B12-FOLATE™

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpsel, spons en sigaliesakkie.

IDENTIFIKASIE VAN INTRINSI B12-FOLATE™

Onbedekte, ronde ligpijn tablet.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

11 Oktober 2024

NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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