

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### HERSYNERGY®, 60 Tablets

#### COMPOSITION

Each one (1) tablet of HERSHEYNERGY® contains the following actives:

Fenugreek ( <i>Trigonella foenum-graecum</i> ) [Seed 33:1 Extract standardized to 150 mg saponin glycosides]	300 mg
Betaine HCl	100 mg
Magnesium (as magnesium citrate)	50 mg
Zinc (as zinc citrate)	2,5 mg
Vitamin B6 (as pyridoxine HCl)	0,5 mg
Folate (as calcium L-5-methyltetrahydrofolate)	198 µg
Vitamin B12 (as methylcobalamin)	1 µg

**Inactive Ingredients:** Coating (hypromellose, maltodextrin, and polyethylene glycol), croscarmellose sodium, microcrystalline cellulose, silica, stearic acid (vegetable).

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

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

HERSYNERGY® is formulated with a unique blend of fenugreek extract, vitamins, and minerals to support women's overall vitality and well-being. This concentrated formula also helps maintain a balanced response to occasional stress and promotes relaxation and emotional well-being.

Ingredient	Uses for Ingredient
Fenugreek ( <i>Trigonella foenum-graecum</i> )	Supports blood sugar regulation, enhances digestive health.
Betaine HCl	Improves stomach acid levels, supports protein digestion, and enhances nutrient absorption.
Magnesium (as magnesium citrate)	Promotes muscle relaxation, supports bone health, and aids in maintaining normal nerve and heart function.
Zinc (as zinc citrate)	Boosts immune system function, supports wound healing, and promotes skin health and reproductive health.
Vitamin B6 (as pyridoxine HCl)	Supports energy metabolism, aids in the synthesis of neurotransmitters, and helps maintain hormonal balance.
Folate (as calcium L-5-methyltetrahydrofolate)	Promotes cellular growth, aids in red blood cell production, and supports healthy foetal development.
Vitamin B12 (as methylcobalamin)	Supports energy production, aids in red blood cell formation, and maintains nervous system health.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take HERSHEYNERGY® 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.

**SURGERY:** HERSHEYNERGY® should be discontinued at least 2 weeks prior to reduce bleeding risks. **ANTIBIOTICS:** HERSHEYNERGY® may reduce the efficacy of antibiotics like fluoroquinolones and tetracyclines if taken together. Take HERSHEYNERGY® two hours before or 4 hours after any antibiotic medication.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Diabetes (can lower blood sugar levels excessively), Peptic ulcers or gastritis (can aggravate symptoms), Severe kidney disease (risk of magnesium toxicity), Heart block or myasthenia gravis (can worsen symptoms), Wilson's disease or copper deficiency (zinc competes with copper for absorption), Cancer patients (can promote cell division in rapidly growing tumours if taken in excess), Leber's disease (hereditary optic neuropathy; B12 can worsen symptoms). If you are taking the following medication, please consult with your healthcare practitioner before taking: Potentiates hypoglycaemic medications (e.g., insulin, metformin), Increases bleeding risk with anticoagulants (e.g., warfarin, aspirin), May enhance the effects of acidifying drugs (e.g., antacids or PPIs, reducing efficacy), Reduces effectiveness of isoniazid, hydralazine, and penicillamine by competing for metabolism, May reduce the effectiveness of methotrexate (used in cancer or autoimmune diseases), May interact with chloramphenicol, reducing the hematologic response to vitamin B12. If any of the following happens, stop using HERSHEYNERGY® 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 HERSHEYNERGY®. 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):

- Gastrointestinal discomfort, heartburn, nausea, vomiting..

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 twice daily with food or as advised by your healthcare practitioner. **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 HERSHEYNERGY® if you notice visible signs of deterioration.

#### IDENTIFICATION

Light green, coated 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.

Document reference: HRSYN.PLV1 01-25

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## HERSYNERGY®, 60 Tablette

### SAMESTELING

**Elke (1) tablet HERSYNERGY® bevat die volgende aktiewe stowwe:**

Fenegriek ( <i>Trigonella foenum-graecum</i> ) [Saad 33:1 Uittreksel gestandaardiseer tot 150 mg sapienliglosiede]	300 mg
Betaine HCl	100 mg
Magnesium (as magnesiumsitraat)	50 mg
Sink (as sinkisitraat)	2,5 mg
Vitamiën B6 (as piridoksien HCl)	0,5 mg
Folaat (as kalsium L-5-metietetrahidrofolaat)	198 µg
Vitamiën B12 (as metielkobalamien)	1 µg

**Onaktiewe bestanddele:** Laag (hipromellose, maltodextrine, en polietileneenglikol), kroskarmelloseennatrium, mikrokrystallyn sellulose, silika, steariensuur (groente).

**Hierdie produk is geskik vir vegetariërs, suiwel- en glutenvry en nie-GGO.**

**(Suikevry)**

### FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**HERSYNERGY®** is geformuleer met 'n unieke mengsel van fenegriek-uittreksel, vitamien en minerale om vroeë se algehele lewenskragtigheid en welstand te ondersteun. Hierdie gekonsentreerde formule help ook om 'n gebalanseerde reaksie op af en toe stres te handhaaf en bevorder ontspanning en emosionele welstand.

Bestanddeel	Gebruik vir bestanddeel
Fenegriek ( <i>Trigonella foenum-graecum</i> )	Ondersteun bloedsuikerregulering, verbeter spysverteringstelsel gesondheid.
Betaine HCl	Verbeter maagsuurvlakke, ondersteun proteïenvertering en verhoog voedingstofabsorpsie.
Magnesium (as magnesiumsitraat)	Bevorder spierverslapping, ondersteun beengesondheid en help met die handhawing van normale senuwee- en hartfunksie.
Sink (as sinkisitraat)	Verhoog immuunstelselfunksie, ondersteun wondgenesing en bevorder velgesondheid en voortplantingsgesondheid.
Vitamiën B6 (as piridoksien HCl)	Ondersteun energiemetabolisme, help met die sintese van neurotransmitters en help om hormonale balans te handhaaf.
Folaat (as kalsium L-5-metietetrahidrofolaat)	Bevorder sellulêre groei, help met rooibloedselproduksie en ondersteun gesonde fetale ontwikkeling.
Vitamiën B12 (as metielkobalamien)	Ondersteun energieproduksie, help met rooibloedselvorming, en handhaaf senuweestelsel gesondheid.

### KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **HERSYNERGY®** 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. **CHIRURGIE:** **HERSYNERGY®** moet ten minste 2 weke voor chirurgie om die vermindering van bloedingrisiko's gestaak word. **ANTIBIOTIKA:** **HERSYNERGY®** kan die doeltreffendheid van antibiotika soos fluorokinolone en tetrasikline verminder as dit saam geneem word. Neem **HERSYNERGY®** twee uur voor of 4 uur na enige antibiotiese medisyne.

### WAARSKOWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Diabetes (kan bloedsuikervlakke oormatig verlaag), Maagseer of gastritis (kan simptome vererger), Ernstige niersiekte (risiko van magnesiumtoksiteit), Hartbolk of myasthenia gravis (kan simptome vererger), Wilson se siekte of kopertekort (sink kompeteer met koper vir absorpsie), Kankerpatiënte (kan seldeling in vinnig groeiende gewasse bevorder as dit in oormaat geneem word), Leber se siekte (oorerflikte optiese neuropatie; B12 kan simptome vererger). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Versterk hipoglisemiese medisyne (bv. insulien, metformien), Verhoog bloedingrisiko met antikoagulant (bv. warfarin, aspirien), Kan die effek van versurende middels verbeter (bv. teensuurmiddels of PPI's, verminder doeltreffendheid), Verminder doeltreffendheid van isoniazid, hyalerasien en penisillamien deur mee te ding vir metabolisme, Kan die doeltreffendheid van metotreksaat verminder (gebruik in kanker of outo-immun siektes), Kan interaksie hê met chloroamfenikol, wat die hematologiese reaksie op vitamien B12 verminder.

As enige van die volgende gebeur, hou op om **HERSYNERGY®** 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 **HERSYNERGY®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- Gastro-intestinale ongemak, soorbrand, naarheid, braking. Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **HERSYNERGY®** 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 GEBUIK 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 **Waarskrywings** en **Spesiale voorsorgmatreëls**)

### DOSES EN AANWYSINGS VIR GEBUIK

**Volwassenes** Neem daaglik een (1) kapsule of soos aanbeveel deur

jou gesondheidspraktisyn.

**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 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.

### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

### Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander

gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

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

Beskerk teen direkte sonlig en hitte.

Bêre in die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermer dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui

word nie.

Moenie **HERSYNERGY®** gebruik as u sigbare tekens van agteruitgang

opmerk nie.

### IDENTIFIKASIE

Liggroen, bedekte tablet.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêl,

peuterkrimpsêl, spons en silikagelsakke.

### 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 BESIGHEIDSDRES VAN APLIKANT

#### Verprei deur:

Ampiro 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.