

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### METHYLCARE®, 60 Capsules

#### COMPOSITION

Each one (1) capsule of METHYLCARE® contain the following actives:

L-cysteine (as N-acetyl-L-cysteine)	300 mg
Betaine (as betaine HCl)	250 mg
Vitamin B6 (as pyridoxal-5-phosphate)	12,5 mg
Vitamin B2 (as riboflavin)	800 µg
Zinc (as zinc citrate)	750 µg
Folate (as calcium L-5-methyltetrahydrofolate)	500 µg
Manganese (as manganese citrate)	200 µg
Vitamin B12 (as methylcobalamin)	100 µg
Molybdenum (as sodium molybdate)	7,5 µg

**Inactive Ingredients:** Dicalcium phosphate, hydroxypropyl methyl cellulose, magnesium carbonate, magnesium salts of fatty acids, microcrystalline cellulose and silicon dioxide.

**This product is dairy and gluten free and is non-GMO. (Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**METHYLCARE®** is a comprehensive formula that features calcium L-5-methyltetrahydrofolate—a body-ready, nature identical folate—along with N-acetyl-L-cysteine, vitamins B6 and methylated B12, and betaine HCl. Together, these nutrients support methylation, which promotes healthy homocysteine metabolism.

Ingredient	Use for Ingredient
L-cysteine (as N-acetyl-L-cysteine)	Supports detoxification and protects cells from oxidative stress
Betaine (as betaine HCl)	Supports methylation and helps improve liver function and digestion.
Vitamin B6 (as pyridoxal-5-phosphate)	Essential for proper methylation processes and the conversion of homocysteine to methionine.
Vitamin B2 (as riboflavin)	Supports methylation pathways and helps in the conversion of other B vitamins.
Zinc (as zinc citrate)	Aids in methylation and supports the enzymatic reactions needed for healthy DNA synthesis.
Folate (as calcium L-5-methyltetrahydrofolate)	Provides active folate for methylation processes and homocysteine metabolism.
Manganese (as manganese citrate)	Supports methylation and antioxidant function to protect cells from oxidative damage.
Vitamin B12 (as methylcobalamin)	Essential for methylation, DNA synthesis, and maintaining normal homocysteine levels.
Molybdenum (as sodium molybdate)	Supports the breakdown of sulfur-containing amino acids and enhances methylation reactions.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **METHYLCARE®** 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:** **METHYLCARE®** should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:** **METHYLCARE®** may interfere with certain function/deficiency tests. Please tell your healthcare practitioner that you are taking **METHYLCARE®** before having any laboratory tests. **ANTIBIOTICS:** **METHYLCARE®** may bind with antibiotics like tetracyclines and fluoroquinolones, reducing their effectiveness. Administer these supplements 2-4 hours before or after taking antibiotics.

#### 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**)

#### DOSE AND DIRECTIONS FOR USE

**Adults:** Take one (1) capsule, once daily or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

#### 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.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Gastric ulcers, acid reflux, or gastrointestinal issues. Caution in individuals with neuropathy or history of nerve damage. If you are taking the following medication, please consult with your healthcare practitioner before taking: Nitro-glycerine: May enhance the effects of nitro-glycerine, leading to hypotension, Antacids: May reduce effectiveness of betaine HCl as stomach acid is neutralized, Levodopa (Parkinson's disease treatment): May reduce effectiveness of levodopa, Antipsychotics: May interfere with the absorption of vitamin B2 in individuals on long-term antipsychotic therapy, Antibiotics (e.g., tetracyclines, quinolones): Zinc may interfere with the absorption of certain antibiotics, Anticonvulsants (e.g., phenytoin, carbamazepine): May reduce the effectiveness of anticonvulsant medications, Iron supplements: High iron levels can interfere with manganese absorption, Metformin: May reduce B12 absorption, leading to deficiency.



If any of the following happens, stop using **METHYLCARE®** 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).

These are all very serious effects. If you have them, you may have had a serious reaction to **METHYLCARE®**. 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):

- Nausea, upset stomach, vomiting, metallic taste in the mouth, yellow/orange urine.

These are all very serious effects. If you have them, you may have had a serious reaction to **METHYLCARE®**. 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.

#### 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 **METHYLCARE®** if you notice visible signs of deterioration.

#### IDENTIFICATION

Capsule.

#### PRESENTATION

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

#### 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.

**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  
Galaxy Park, Unit 5B  
Galaxy Avenue, Limbro Park  
Sandton, 2090, Tel: 011-802-8101

#### DATE OF PUBLICATION

To be allocated by the regulatory authority.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

## METHYLCARE®, 60 Kapsules

### SAMESTELING

Elke een (1) kapsule van METHYLCARE® bevat die volgende aktiewe stowwe:

L-sistein (as N-asetiel-L-sistein)	300 mg
Betaïne (as betaïen HCl)	250 mg
Vitamien B6 (as piridoksaal-5-fosfaat)	12,5 mg
Vitamien B2 (as riboflavin)	800 µg
Sink (as sinkstraat)	750 µg
Folaat (as kalsium L-5-metiletetrahydrofolaat)	500 µg
Mangaan (as mangaansitraat)	100 µg
Vitamien B12 (as metielkobalamien)	100 µg
Molibdeen (as natriummolibdaat)	7,5 µg

**Onaktiewe bestanddele:** Dikalsiumfosfaat, hidrosipropylmetielcellulose, magnesiumkarbonaat, magnesiumsoute van vetsure, mikrokristallyne sellulose en silikondioksied.

**Hierdie produk is suiwel- en glutenvry en is nie-GGO. (Suikerervy)**

### FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**METHYLCARE®** is 'n omvattende formule wat kalsium L-5-metiletetrahydrofolaat bevat - 'n liggaamsgeerd, natuuridentiese folaat - saam met N-asetiel-L-sistein, vitamien B6 en gemetleerde B12, en betaïne HCl. Saam ondersteun hierdie voedingstowwe mettering, wat gesond bevorder homosistein metabolisme.

Bestanddeel	Gebruik vir bestanddeel
L-sistein (as N-asetiel-L-sistein)	Ondersteun ontgifting en beskerm selle teen oksidatiewe stres
Betaïne (as betaïen HCl)	Ondersteun mettering en help om lewerfunksie en spysvertering te verbeter.
Vitamien B6 (as piridoksaal-5-fosfaat)	Noodsaaklik vir behoorlike metteringsprosesse en die omskakeling van homosistein na metionien.
Vitamien B2 (as riboflavin)	Ondersteun metteringsweë en help met die omskakeling van ander B-vitamiene.
Sink (as sinkstraat)	Help met mettering en ondersteun die ensiematiese reaksies wat nodig is vir gesonde DNA-sintese.
Folaat (as kalsium L-5-metiletetrahydrofolaat)	Verskaf aktiewe folaat vir metteringsprosesse en homosisteinmetabolisme.
Mangaan (as mangaansitraat)	Ondersteun mettering en antioksidantfunksie om selle teen oksidatiewe skade te beskerm.
Vitamien B12 (as metielkobalamien)	Noodsaaklik vir mettering, DNA-sintese en die handhawing van normale homosisteïenvlakke.
Molibdeen (as natriummolibdaat)	Ondersteun die afbreek van swaelbevattende aminosure en verhoog metteringsreaksies.

### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **METHYLCARE®** 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: METHYLCARE®** moet ten minste 2 weke voor die tyd gestaak word om bloedingrisiko's te verminder. **LABORATORIUMTOETS:**

**METHYLCARE®** kan inmeng met sekere funksie/tektortoe. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **METHYLCARE®** neem voordat enige laboratoriumtoets ondergaan word. **ANTIBIOTIKA: METHYLCARE®** kan bind met antibiotika soos tetraskilene en fluoroquinolone, wat hul doeltreffendheid verminder. Dien hierdie aanvullings 2-4 ure toe voor of na die neem van antibiotika.

### INTERAKSIE

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

### DOSES EN AANWYSINGS VIR GEBRUIK

**Volwassenes:** Neem een (1) kapsule, een keer per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedignoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Maagere, suur reflux of gastro-intestinale probleme. Wees versigtig by individue met neuropatie of geskiedenis van senuweeskaede. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Nitro-gliserien: Kan die effekte van nitro-gliserien verbeter, wat lei tot hipotensie, Teensuurmiddels: Kan die doeltreffendheid van betaïne HCl verminder aangesien maagsuur geneutraliseer word, Levodopa (behandeling van Parkinson se siekte): Kan die doeltreffendheid van levodopa verminder, Antipsigotika: Kan inmeng met die absorpsie van vitamien B2 by individue op langtermyn antipsigotiese terapie, Antibiotika (bv. tetraskilene, kinolone): Sink kan inmeng met die absorpsie van sekere antibiotika, Antikonvulsante (bv. fenitoien, karbamazepien): Kan die doeltreffendheid van antikonvulsante medikasie verminder, Ysteraanvullings: Hoë ystervlakke kan inmeng met mangaanabsorpsie, Metformien: Kan B12-absorpsie verminder, wat lei tot tekort. As enige van die volgende gebeur, hou op om **METHYLCARE®** 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);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **METHYLCARE®** 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):

- Naarheid, omgekrapte maag, braking, metaalmaak in die mond, geel / oranje urine.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **METHYLCARE®** 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 apteeker 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.
  - As jy moet nie hierdie produk aanvaar as seëls gebreek word 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, apteeker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteeker of gesondheidsorgpraktisyn in kennis.

### BEKENDE SIMPTOME VAN OORDOSEERING EN BESONDERHEDE VAN DIE

**BEHANDELING DAARVAN** Sien nuwe-effekte.

**Behandeling:** Staak gebruik en raadpleeg jou dokter, apteeker of ander gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

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

Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermdede dop na elke gebruik.

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

Moenie **METHYLCARE®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Kapsule.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêel, peuterkrimpêel, 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 BESIGHEIDSDRES VAN APPLIKANT

**Versprei deur:**

Amipro Advanced Development Products (Pty) Ltd

Galaxy Park, Unit 5B

Galaxy Avenue, Limbro Park

Sandton, 2090, Tel: 011- 802-8101

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

