

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS <sup>50</sup>

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

## METHYLCARE<sup>®</sup>, 60 Capsules

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

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

### WHAT IS IN THIS LEAFLET

- What **METHYLCARE<sup>®</sup>** is and what it is used for.
- What you need to know before you take **METHYLCARE<sup>®</sup>**.
- How to take **METHYLCARE<sup>®</sup>**.
- Possible side effects.
- How to store **METHYLCARE<sup>®</sup>**.
- Contents of the pack and other information.

### WHAT METHYLCARE<sup>®</sup> CONTAINS

Each one (1) capsule of **METHYLCARE<sup>®</sup>** 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)**

### WHAT METHYLCARE<sup>®</sup> IS AND WHAT IT IS USED FOR

**METHYLCARE<sup>®</sup>** 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.

### BEFORE YOU TAKE METHYLCARE<sup>®</sup>

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

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

### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not 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 **METHYLCARE<sup>®</sup>** 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 **METHYLCARE<sup>®</sup>** may affect you.

### TAKING OTHER MEDICINES WITH METHYLCARE<sup>®</sup>

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 medical practitioner.

### 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.**

### IF YOU TAKE MORE METHYLCARE<sup>®</sup> THAN YOU SHOULD

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

### IF YOU FORGET TO TAKE METHYLCARE<sup>®</sup>

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



### HOW TO TAKE METHYLCARE<sup>®</sup>

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

### POSSIBLE SIDE EFFECTS

**METHYLCARE<sup>®</sup>** may have side effects.

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<sup>®</sup>** 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<sup>®</sup>**. 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.

Not all side effects and interactions reported for **METHYLCARE<sup>®</sup>** 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/B>. By reporting side effects, you can help provide more information on the safety of **METHYLCARE<sup>®</sup>**.

### STORAGE AND DISPOSING OF METHYLCARE<sup>®</sup>

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 **METHYLCARE<sup>®</sup>** if you notice visible signs of deterioration.

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

### PRESENTATION OF METHYLCARE<sup>®</sup>

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

### IDENTIFICATION OF METHYLCARE<sup>®</sup>

Capsule.

### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

### THIS LEAFLET WAS LAST REVISED ON

25 September 2025

### NAME AND ADDRESS OF REGISTRATION HOLDER

#### Distributed by:

Amipro Advanced Development Products (Pty) Ltd  
Galaxy Park, Unit 5B  
Galaxy Avenue, Limbro Park  
Sandton, 2090, Tel: 011-802-8101



# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulase

HANDELSNAAM EN DOSEERVORM,

## METHYLCARE<sup>®</sup>, 60 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

### BELANGRIKE INLIGTING VIR U

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

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **METHYLCARE<sup>®</sup>** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **METHYLCARE<sup>®</sup>** neem.
- Hoe om **METHYLCARE<sup>®</sup>** te neem.
- Moontlike nuwe-effekte.
- Hoe om **METHYLCARE<sup>®</sup>** te bêre.
- Inhoud van die pak en ander inligting

### WATTER METHYLCARE<sup>®</sup> BEVAT

Elke een (1) kapsule **METHYLCARE<sup>®</sup>** bevat die volgende aktiewe:

L-sistein (as N-asetiel-L-sistein)	300 mg
Betaïene (as betaïen HCl)	250 mg
Vitamiën B6 (as piridoksaal-5-fosfaat)	12,5 mg
Vitamiën B2 (as riboflaviën)	800 µg
Sink (as sinksteraat)	750 µg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	500 µg
Mangaan (as mangaansitraat)	200 µg
Vitamiën B12 (as metielkobalamin)	100 µg
Molibdeen (as natriummolibdaat)	7,5 µg

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

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

### WAT IS METHYLCARE<sup>®</sup> KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**METHYLCARE<sup>®</sup>** is 'n omvattende formule wat kalsium L-5-metiltetrahidrofolaat bevat - 'n liggaamsgereed, natuurdiëtiese folaat - saam met N-asetiel-L-sistein, vitamien B6 en gemetleerde B12, en betaïen HCl. Saam ondersteun hierdie voedingsstowwe mettering, wat gesond bevorder homosistein metabolisme.

### VOORDAT JY METHYLCARE<sup>®</sup> NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisy te raadpleeg nie. Moenie **METHYLCARE<sup>®</sup>** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou **CHIRURGIE: METHYLCARE<sup>®</sup>** moet ten minste 2 weke voor die vermindering van bloedsingsrisiko's gestaak word. **LABORATORIUMTOETS: METHYLCARE<sup>®</sup>** kan inmeng met sekere funksie/tekoortse. Vertel asseblief jou gesondheidsorgpraktisy dat jy **METHYLCARE<sup>®</sup>** neem voordat enige laboratoriumtoets ondergaan word. **ANTIBIOTIKA: METHYLCARE<sup>®</sup>** kan bind met antibiotika soos tetrasielien en fluorokinolone, wat hul doeltreffendheid verminder. Dien hierdie aanvullings 2-4 ure toe voor of na die neem van antibiotika.

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

### BESTUUR EN GEbruik VAN MASJIENE

Dit is nie altyd moontlik om te voorspel in watter mate **METHYLCARE<sup>®</sup>** 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, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **METHYLCARE<sup>®</sup>** jou beïnvloed.

### NEEM VAN ANDER MEDISYNE SAAM MET METHYLCARE<sup>®</sup>

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 gesondheidsorgpraktisy te raadpleeg nie.

### SWANGERSKAP EN BORSOEDING

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

### HOE OM METHYLCARE<sup>®</sup> TE NEEM

Komplementêre medisyne wat vir u voorgeskrif is, met enige ander persoon deel nie. Neem altyd **METHYLCARE<sup>®</sup>** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisy voorgeskrif het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisy as jy onseker is.

### Aanwysings vir gebruik:

**Volwassenes** Neem een (1) kapsule, een keer per dag, of soos voorgeskrif deur jou gesondheidspraktisy.

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

**AS JY MEER METHYLCARE<sup>®</sup> 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 METHYLCARE<sup>®</sup> TE NEEM**

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

### MOONTLIKE NUWE-EFFEKTE

**METHYLCARE<sup>®</sup>** kan nuwe-effekte hê.

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisy voor gebruik: Maagsere, suur reflux of gastro-intestinale probleme. Wees versigtig by individue met neuropatie of geskiedenis van senuweeskade. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisy voordat jy neem: Nitro-gliserien: Kan die effek van nitro-gliserien verbeter, wat lei tot hipotensie. Teensuurmiddels: Kan die doeltreffendheid van betaïene 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. tetrasielien, kinolone): Sink kan inmeng met die absorpsie van sekere antibiotika, Antikonvulsante (bv. fenitoin, karbamazepien): Kan die doeltreffendheid van antikonvulsie medikasie verminder. Ysteraanvullings: Hoë ystervlakke kan inmeng met mangaanabsorpsie, Metformin: Kan B12-absorpsie verminder, wat lei tot te kort. As enige van die volgende gebeure, soos om **METHYLCARE<sup>®</sup>** te gebruik en vertel jou dokter of gaan na die ongevallie-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<sup>®</sup>** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

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

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

Nie alle nuwe-effekte en interaksies wat vir **METHYLCARE<sup>®</sup>** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadadige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisy vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisy in kennis.

### AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisy. 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 **METHYLCARE<sup>®</sup>**.

### HOE OM METHYLCARE<sup>®</sup> TE BÊRE

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker 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 **METHYLCARE<sup>®</sup>** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

### AANBIEDING VAN METHYLCARE<sup>®</sup>

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesel, peuterkrimpseel, spons en silikagelsakke.

### IDENTIFIKASIE VAN METHYLCARE<sup>®</sup>

Kapsule.

### REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESIONELE INLIGTING**

Skaander QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

25 September 2025

**NAAM EN ADRES VAN REGISTRASIEHOUER**

Versprei deur:

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