

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### MITOVICE™, 450 g Powder

#### COMPOSITION

Each one (1) scoop (10 g) of MITOVICE™ contain the following actives:

L-carnitine (as L-carnitine fumarate)	1 g
Tauriune	400 mg
Dicalcium phosphate (providing elemental calcium 41,8 mg and elemental phosphorus 33,3 mg)	218,9 mg
Magnesium (as magnesium bisglycinate)	200 mg
Potassium (as potassium chloride)	200 mg
Vitamin C (as ascorbic acid)	200 mg
Vitamin B3 (as niacinamide)	33,33 mg
Vitamin B6 (as pyridoxine HCl)	33,33 mg
Vitamin B1 (as thiamine mononitrate)	20 mg
Vitamin B2 (as riboflavin)	1,27 mg
Folate (as calcium L-5-methyltetrahydrofolate)	102 µg
Vitamin B12 (as methylcobalamin)	100 µg
Chromium (as chromium picolinate)	33,33 µg
Selenium (as selenomethionine)	16,67 µg

**Inactive Ingredients:** Cellulose, coating (hypromellose, medium-chain

**Contains Sugar:** Organic cane sugar 3,25 g

**Contains Sweetener:** Rebaudioside A (from Stevia rebaudiana leaf extract) 0,024 g

**This product is non-GMO, gluten-free, dairy free.**

**PHARMACOLOGICAL CLASSIFICATION** - Complementary Medicine

**INDICATION & PHARMACOLOGICAL ACTION**

MITOVICE™ is a formula that features a unique blend of lipotropic nutrients combined with select amino acids, vitamins, and a proprietary extract of herbs to support healthy liver and digestive function.

#### CONTRA INDICATIONS:

Caution is advised if you are taking magnesium along with muscle relaxants as this can increase the risk of side effects of muscle relaxants. If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take MITOVICE™ 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.

Ingredients	Uses for ingredient
L-carnitine (as L-carnitine fumarate)	L-carnitine is important for heart and brain function, muscle movement, and many other body processes.
Tauriune	It helps support nerve growth.
Dicalcium phosphate	Dicalcium phosphate is a valuable supplement that provides essential calcium and phosphorus, supporting bone
Magnesium (as magnesium bisglycinate)	It assists in calcium absorption and promotes bone mineralization.
Potassium (as potassium chloride)	Potassium plays an important role in maintaining the health of your kidneys, heart, muscles, and nervous system.
Vitamin C (as ascorbic acid)	It is needed by the body to help wounds heal, to enhance the absorption of iron
Vitamin B3 (as niacinamide)	As a supplement, niacin may help lower cholesterol, ease arthritis, and boost brain function, among other benefits.
Vitamin B6 (as pyridoxine HCl)	Vitamin B6 plays an important role in the body. It is needed to maintain the health of nerves, skin, and red blood cells.
Vitamin B1 (as thiamine mononitrate)	Thiamine helps to turn food into energy and to keep the nervous system healthy.
Vitamin B2 (as riboflavin)	Riboflavin (vitamin B2) plays an important role in maintaining the health of your blood cells, brain, skin, and digestive tract.
Folate (as calcium L-5-methyltetrahydrofolate)	Folate (vitamin B-9) is important in red blood cell formation and for healthy cell growth and function
Vitamin B12 (as methylcobalamin)	Methylcobalamin improves their nerve condition and promotes regeneration of the damaged nerves.
Chromium (as chromium picolinate)	Chromium is an essential mineral that plays a role in how insulin helps the body regulate blood sugar levels.
Selenium (as selenomethionine)	Support for the thyroid gland, heart, immune system and management of healthy cholesterol levels.

**WARNING AND SPECIAL PRECAUTIONS** Contains Organic cane sugar, Rebaudioside A which may have an effect on the glycaemic control of patients with diabetes mellitus. Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Diabetes, Peptic ulcer disease, Acidosis, Hardening of the arteries® (atherosclerosis), Liver disease, including cirrhosis, Methylene tetrahydrofolate reductase (MTHFR) deficiency, Schizophrenia, Alcohol use disorder, Cancer, Chronic kidney disease, A metabolic deficiency called "glucose-6-phosphate dehydrogenase" (G6PD) deficiency, Kidney stones, Bleeding disorders, Heart block, A condition called myasthenia gravis, Kidney problems, such as kidney failure, Bile duct obstruction, Gallstones, Post-surgical stent placement, Weight loss surgery, Seizure disorder Allergic reactions— rash, Itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;



If you are taking the following medication, please consult with your healthcare professional before taking: Atropine, Medications for diabetes (Antidiabetic drugs), Antacids, stomach acid (H2-blockers, Proton pump inhibitors), Estrogens, cancer (Alkylating agents, Antitumor antibiotics), Niacin, Warfarin (Coumadin), Levothyroxine (Synthroid), Acetaminophen (Tylenol), Aspirin, Salsalate (Disalcid), Lithium, high blood pressure (Antihypertensive drugs, Calcium channel blockers), Antibiotics (Aminoglycoside antibiotics), Antibiotics (Quinolone antibiotics), Bisphosphonates, Water pills (Potassium-sparing diuretics), blood clotting (Anticoagulant / Antiplatelet drugs), Digoxin (Lanoxin), Medications for diabetes (Sulfonylureas), Antacids, Gabapentin (Neurontin), Ketamine (Ketaral). If any of the following happens, stop using MITOVICE™ 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 MITOVICE™. 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, diarrhea, and vomiting.

These are all very serious effects. If you have them, you may have had a serious reaction to MITOVICE™. 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

**Adults:** Blend, shake, or briskly stir one (1) scoop (10 g) into 120 to 180 ml of chilled water once daily or as directed 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 MITOVICE™ if you notice visible signs of deterioration.

#### IDENTIFICATION

Light orange, semi-granular powder

#### PRESENTATION

A white 450g jar with a white lid, induction seal, tamper shrink seal.

#### 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: MITO.PL.V1 12-24

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddele Formulasie

HANDELSNAAM EN DOSEERVORM,

**MITOVIVE™, 450g Poer**

## SAMESTELING

Elke een (1) lepel (10 g) MITOVIVE™ bevat die volgende aktiewe stowwe:

L-kartiniën (as L-kartiniën fumarate)	1 g
Stier	400 mg
Dikalsiumfosfaat (verskaf elementêre kalsium 41,8 mg en elementêre fosfor 33,3 mg)	218,9 mg
Magnesium (as magnesiumbisglycinaat)	200 mg
Kalium (as kaliumchloried)	200 mg
Vitamiën C (as askorbiensuur)	200 mg
Vitamiën B3 (as niacinaamide)	33,33 mg
Vitamiën B6 (as piridoksien HCl)	33,33 mg
Vitamiën B1 (as tiamienmononitraat)	20 mg
Vitamiën B2 (as riboflaviën)	1,27 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	102 µg
Vitamiën B12 (as metielkobalamin)	100 µg
Chroom (as chroompikolinaat)	33,33 µg
Selenium (as selenometionien)	16,67 µg

**Onaktiewe bestanddele: Onaktiewe bestanddele:** Anatto-uitreksel (kleur), natuurlike geure en silika.

**Bevat suiker:** Organiese rietsuiker 3,25 g

**Bevat versoeter:** Rebaudioside A (van Stevia rebaudiana-blaar uitreksel) 0,024 g

**Hierdie produk is nie-GGO, glutenvry.**

**FARMAKOLOGIESE KLASSIFIKASIE** - Komplementêre medisyne

**AANDUIDING EN FARMAKOLOGIESE WERKING**

**MITOVIVE™** verskaf 'n mengsel van voedingstowwe, insluitend aminosure soos as L-kartiniën en Taurine, saam met magnesium, geformuleer om Ondersteun algehele welstand, energiemetabolisme en spierherstel.

## KONTRA-INDIKASIES:

Wees versigtig as jy magnesium saam met spierverslappers neem, aangesien dit die risiko van nuwe-effekte van spierverslappers kan verhoog. As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie MITOVIVE™ neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem.

## WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Bevat organiese rietsuiker, Rebaudioside A wat 'n effek kan hê op die glukemiese beheer van pasiënte met diabetes mellitus. Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn vir gebruik: Suikersiekte, Maagserieseiekte, Asidose, Verharding van die are (aterosklerose), Lewersiekte, insluitend sirroos, Metielteetrahydrofolaatreduktase (MTHFR) tekort, Skisofrenie, Alkoholgebruiksversteuring, Kanker, Chroniese niersiekte, 'n metaboliese tekort genaamd "glukose-6-fosfaat dehidrogenase" (GGPD) tekort, Nier stene, Bloedingsversteurings, Hartbloeke, 'n Toestand genaamd myasthenia gravis, Nierprobleme, soos nierversaking, galbuisobstruksie, galstene, post-chirurgiese stentplasing, gewigsverlieschirurgie, beslagleggingsversteuring. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Teensuurmiddels, maagsuur (H2-blokkers, Protonpomp remmers), Estrogeen, kanker (Alkylleermiddels, Antitumor antibiotika), Niasien, Warfarin (Coumadin), Levothyroxine (Synthroid), Acetaminophen (Tylenol), Aspirien, Salsalate (Disalid), Litium, hoë bloeddruk (Antihypertensiewe middels, Kalsiumkanaalblokkers), Antibiotika (Aminoglikosiedantibiotika), Antibiotika (Kinolonantibiotika), Bisfosfonate, Waterpille (Kaliumbesparende diuretika), bloedstolling (Antikoagulant / Antiplatelet middels), Digoxin (Lanoxin), medisyne vir diabetes (Sulfonylureas), Teensuurmiddels, Gabapentien (Neurontin), Ketamien (Ketalar). As enige van die volgende gebeur, hou op om MITOVIVE™ 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 MITOVIVE™ 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):

- Sweet, 'n visagtige liggamsreuk, diarree en braking Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op MITOVIVE™ 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 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.

## INTERAKSIES

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**)

## DOSIS EN AANWYSINGS VIR GEBRUIK

**Volwasse** - Meng, skud of roer vinnig een (1) lepel (10 g) in 120 tot 180 ml verkoelde water een keer per dag of soos aangedui 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 tydens die gebruik van hierdie aanvulling, 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

Hou dig toegemaak op 'n koel, droë plek, onder 25 °C.

Beskermer teen direkte sonlig en hitte.

Bêre n 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 MITOVIVE™ gebruik as u sigbare tekens van agteruitgang opmerk nie.

## IDENTIFIKASIE

Ligte oranje, semi-korrelvormige poer.

## AANBIEDING

'n Wit pot van 450 g met 'n wit deksel.

## 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 BESIGHEIDSADRES VAN APPLIKANT

### Versprei 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.

Bestanddele	Gebruik vir bestanddeel
L-kartiniën (as L-kartiniën fumarate)	L-kartiniën is belangrik vir hart- en breinfunksie, spierbeweging en baie ander liggamsprosesse.
Stier	Dit help om senuweegroei te ondersteun.
Dikalsiumfosfaat	Dikalsiumfosfaat is 'n waardevolle aanvulling wat noodsaaklike kalsium en fosfor verskaf, wat beengesondheid
Magnesium (as magnesiumbisglycinaat)	Dit help met kalsiumabsorpsie en bevorder beëmineralisasie.
Kalium (as kaliumchloried)	Kalium speel 'n belangrike rol in die handhawing van die gesondheid van jou niere, hart, spiere en senuweestelsel.
Vitamiën C (as askorbiensuur)	Dit is nodig deur die liggaam om wonde te help genees, om die opname van yster
Vitamiën B3 (as niacinaamide)	As 'n aanvulling kan niasien help om cholesterol te verlaag, artritis te verlig en breinfunksie 'n hupstoot te gee, onder andere voordele.
Vitamiën B6 (as piridoksien HCl)	Vitamiën B6 speel 'n belangrike rol in die liggaam. Dit is nodig om die gesondheid van senuwees, vel en rooilbloedselle te handhaaf.
Vitamiën B1 (as tiamienmononitraat)	Tiamien help om voedsel in energie te verander en om die senuweestelsel gesond te hou.
Vitamiën B2 (as riboflaviën)	Riboflaviën (vitamiën B2) speel 'n belangrike rol in die handhawing van die gesondheid van jou bloedselle, brein, vel en spysverteringskanaal.
Folaat (as kalsium L-5-metiltetrahidrofolaat)	Folaat (vitamiën B-9) is belangrik in die vorming van rooilbloedselle en vir gesonde selgroei en funksie
Vitamiën B12 (as metielkobalamin)	Metielkobalamin verbeter hul senuweetoestand en bevorder wedergeboorte van die beskadigde senuwees.
Chroom (as chroompikolinaat)	Chroom is 'n noodsaaklike mineraal wat 'n rol speel in hoe insulien die liggaam help om bloedsuikervlakke te reguleer.
Selenium (as selenometionien)	Ondersteuning vir die tiroiedklier, hart, immuunstelsel en bestuur van gesonde cholesterolvlakke.