

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

MITOVICE™, 450 g Powder

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

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

WHAT IS IN THIS LEAFLET

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

WHAT MITOVICE™ CONTAINS

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

L-carnitine (as L-carnitine fumarate)	1 g
Taurine	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: Annatto extract (colour), natural flavors and silica.

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.

WHAT MITOVICE™ IS AND WHAT IT IS USED FOR

MITOVICE™ provides a blend of nutrients, including amino acids such as L-carnitine and Taurine, along with magnesium, formulated to support overall wellness, energy metabolism and muscle recovery.

BEFORE YOU TAKE MITOVICE™

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 practitioner. 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.

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

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF MITOVICE™

MITOVICE™ contains Organic cane sugar, Rebaudioside A. If you have been told that you have an intolerance to some sugars, you should not take **MITOVICE™**.

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, do not take if you are pregnant or breastfeeding. 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 **MITOVICE™** 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 **MITOVICE™** may affect you.

TAKING OTHER MEDICINES WITH MITOVICE™

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 practitioner.

HOW TO TAKE MITOVICE™

Do not share medicines prescribed for you with any other person. Always take **MITOVICE™** exactly as described in this leaflet, or as your doctor, healthcare practitioner has instructed you. You should check with your doctor, pharmacist or healthcare practitioner if you are unsure.

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.

IF YOU TAKE MORE MITOVICE™ 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 MITOVICE™

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

POSSIBLE SIDE EFFECTS

MITOVICE™ may have side effects.

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.

If you are taking the following medication, please consult with your healthcare practitioner before taking: Atropine, Medications for diabetes (Antidiabetes drugs), Antacids, stomach acid (H2-blockers, Proton pump inhibitors), Estrogens, cancer (Alkylating agents, Antitumor antibiotics), Niacin, Warfarin (Coumadin), Levothyroxine (Synthroid), Acetaminophen (Tylenol), Aspirin, Salsalate (Disalid), 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 (Ketalar). 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.

Not all side effects and interactions reported for **MITOVICE™** 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 **MITOVICE™**.

STORAGE AND DISPOSING OF MITOVICE™

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 **MITOVICE™** if you notice visible signs of deterioration. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF MITOVICE™

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

IDENTIFICATION OF MITOVICE™

Light orange, semi-granular powder.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

19 November 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101



PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.
Disipliene: Gesondheidsaanvulling
34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

MITOVIVE™, 450g Poeier

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER MITOVIVE™ BEVAT

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

L-karnitien (as L-karnitienfumarate)	1 g
Stier	400 mg
Dikalsiumfosfaat (versak 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 askorbien suur)	200 mg
Vitamiën B3 (as niacinamide)	33,33 mg
Vitamiën B6 (as piridoksin HCl)	33,33 mg
Vitamiën B1 (as tiamienmononitraat)	20 mg
Vitamiën B2 (as riboflavin)	1,27 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	102 µg
Vitamiën B12 (as metielkobalamien)	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: Rebadioside A (van Stevia rebadiana-blaar uitreksel) 0,024 g

Hierdie produk is nie-GMO, glutenvry

WAT IS MITOVIVE™ KAPSULES EN WAARVOOR WORD DIT GEBRUIK
MITOVIVE™ verskaf 'n mengsel van voedingstowwe, insluitend aminosure soos as L-karnitien en Taurine, saam met magnesium, geformuleer om Ondersteun algehele welstand, energiemetabolisme en spierherstel.

BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN MITOVIVE™

MITOVIVE™ bevat organiese rietsuiker, Rebadioside A. As daar vir jou gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, moet jy nie **MITOVIVE™** neem nie.

VOORDAT JY MITOVIVE™ NEEM

Wees versigtig as jy magnesium saam met spierverslappers neem, aangesien dit die risiko van neef-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 voordat jy hierdie aanvulling neem.

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

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, moenie neem as jy swanger is of borsvoed nie. 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 MASJIENE

Dit is nie altyd moontlik om te voorspel in watter mate **MITOVIVE™** 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 **MITOVIVE™** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET MITOVIVE™

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 MITOVIVE™ TE NEEM

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

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.

AS JY MEER MITOVIVE™ 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 MITOVIVE™ TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

MITOVIVE™ kan nuwe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Suikersiekte, Maagresiesiekte, Asidose, Verharding van die are* (atrosklerose), Lewersiekte, insluitend sirroze, Metleentetrahydrofolaatreduktase (MTHFR) tekort, Skisofrenie, Alkoholgebruiksversteuring, Kanker, Chroniese niersiekte, 'n metaboolse tekort genaamd 'glukose-6-fosfaat dehidrogenase' (G6PD) tekort, Nier stene, Bloedingsversteurings, Hartbloeke, 'n Toestand genaamd myasthenia gravis, Nierprobleme, soos nierversaking, galblusobstruksie, galstene, post-chroniese stentplasing, gewigsverlieschirurgie, beslagleggingsversteuring.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Atropien, Medikasie vir diabetes (Antidiabetes dwelms), Teensuurmiddels, maagsuur (H2-blokkers, Protonpomp remmers), Alkyleryngsmiddels, Antitumor antibiotika, Niasien, Warfarin (Coumadin), Levothyroxine (Synthroid), Acetaminophen (Tylenol), Aspirien, Salsalate (Disalcol), Litium, hoë bloeddruk (Antihypertensiewe middels, Kalsiumkanaalblokkers), Acetaminophen (Aminoglykosiedantibiotika), Antibiotika (Kinolonantibiotika), Bisfosfonate, Waterpille (Kaliumbesparende diuretika), bloedstolling (Antikoagulant / Antiplatelet middels), Digoxin (Lanoxin), Medikasie 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 (veran van die gesig / tong / keel), erge duiseligheid, probleme met asemaling;

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

- Naarheid, diarree en braking.

Nie alle nuwe-effekte en interaksies wat vir **MITOVIVE™** 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 aantlyk 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 **MITOVIVE™**.

HOE OM MITOVIVE™ TE BÊRE

Hou buite bereik van kinders.

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

Beskerem 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 **MITOVIVE™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN MITOVIVE™

'n Wit pot van 450 g met 'n wit deksel, induksiesel, peuterkrimpsel.

IDENTIFIKASIE VAN MITOVIVE™

Ligte oranje, semi-korrelvormige poeier.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101



