

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.6 Fats, Oils and Fatty Acids

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### META LIPOATE® , 60 Tablets

#### COMPOSITION

Each one (1) tablet of META LIPOATE® contain the following actives:  
Alpha Lipoic Acid 300 mg

**Inactive Ingredients** Magnesium stearate (vegetable), microcrystalline cellulose and silica.

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

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**META LIPOATE®** is known for its antioxidant properties.

This formulation may support overall health and wellness by contributing to the body's antioxidant defences and promoting a balanced metabolic environment.

#### Ingredients

Alpha Lipoic Acid

#### Uses for ingredient

Acts as a potent antioxidant, supports glucose metabolism, and helps manage oxidative stress and nerve health.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **META LIPOATE®** 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:** **META LIPOATE®** should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:** Active ingredients in **META LIPOATE®** may alter the results of tests. Please tell your healthcare practitioner that you are taking **META LIPOATE®** before having any laboratory tests.

#### 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 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: **Thiamine (Vitamin B1) deficiency:** Risk of lactic acidosis, especially in individuals with chronic alcoholism, **Thyroid disorders:** May interfere with thyroid hormone levels or treatments, **Low blood sugar (hypoglycaemia):** Can enhance insulin sensitivity, leading to reduced blood sugar levels, especially in diabetics. If you are taking the following medication, please consult with your healthcare professional before taking: **Antidiabetic drugs (e.g., insulin, metformin):** Can enhance glucose-lowering effects, increasing the risk of hypoglycaemia, **Thyroid medications (e.g., levothyroxine):** May reduce thyroid hormone levels; requires monitoring, **Cisplatin (chemotherapy drug):** May reduce the efficacy of cisplatin, **Alcohol:** Chronic use of alcohol may exacerbate ALA-related risks, especially in thiamine-deficient individuals. If any of the following happens, stop using META LIPOATE® 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 **META LIPOATE®**. 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 issues, metallic taste in the mouth
  - These are all very serious effects. If you have them, you may have had a serious reaction to **META LIPOATE®**. 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 **META LIPOATE®** if you notice visible signs of deterioration.

#### IDENTIFICATION

Off-white with yellow speckles, uncoated oval tablet.

#### PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink 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  
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.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

## META LIPOATE®, 60 Tablette

### SAMESTELING

Elke een (1) tablet van META LIPOATE® bevat die volgende aktiewe stowwe:

Alfa Lipoënsuur	300 mg
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**Onaktiewe bestanddele:** Magnesiumstearaat (groente), mikrokristallyne sellulose en silika.

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

### FARMAKOLOGIESE KLASSEFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**META LIPOATE®** is bekend vir sy antioksidante eienskappe.

Hierdie formulering kan algemene gesondheid en welstand ondersteun deur dra by tot die liggaam se antioksidante verdediging en bevorder 'n gebalanseerde metaboolse omgewing.

#### Bestanddele

Alfa Lipoënsuur

#### Gebruik vir bestanddele

Dien as 'n kragtige antioksidant, ondersteun glukosemetabolisme en help om oksidatiewe stres en senouwegesondheid te bestuur.

### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **META LIPOATE®** 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: META LIPOATE®** moet ten minste 2 weke voor die tyd gestaak word om bloedingsrisiko's te verminder. **LABORATORIUMTOETSE: Aktiewe bestanddele in META LIPOATE®** kan die resultate van toetse verander. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **META LIPOATE®** neem voordat enige laboratoriumtoetse ondergaan word.

### 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

**Volwassenes:** Neem daaglik een (1) tablet of soos voorgeskryf deur jou gesondheidspraktisyn.

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

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

### WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Tiamien (vitamien B1) tekort: Risiko van melksuurdose, veral by individue met chroniese alkoholisme, Skildklierafwykings: Kan inname van triëdrohormoonvlakke of behandelings, Lae bloedsuiker (hipoglukemie): Kan insulieniensitiewiteit verhoog, wat lei tot verlaagde bloedsuikervlakke, veral by diabeete. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Kan glukoseverlagende effekte verbeter, wat die risiko van hipoglukemie verhoog, Skildkliermedikasie (bv. vereis monitering, Cisplatien (chemoterapiemiddel)): Kan die doeltreffendheid van cisplatien verminder, Alkohol: Chroniese gebruik van alkohol kan ALA-ervante risiko's vererger, veral by individue met 'n tekort aan tiamien. As enige van die volgende gebeur, hou op om **META LIPOATE®** te gebruik en vertel jou dokter of gaan na die ongevallende 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 **META LIPOATE®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Gastrointestinale probleme, metaalsmaak in die mond., Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **META LIPOATE®** 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.

### 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.

Beskermt 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 **META LIPOATE®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Naaswit met geel spikkels, onbedekte ovaal tablet.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesieël, peuterkrimpseël, 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 BESIGHEIDSADRES VAN APPLIKANT

#### Versprei deur:

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