

PATIENT INFORMATION LEAFLET

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

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

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

WHAT IS IN THIS LEAFLET

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

WHAT META LIPOATE® CONTAINS

Each one (1) tablet of **META LIPOATE®** contain the following actives:

Alpha Lipic 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)

WHAT META LIPOATE® IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE META LIPOATE®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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 **META LIPOATE®** 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 **META LIPOATE®** may affect you.

TAKING OTHER MEDICINES WITH META LIPOATE®

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.



HOW TO TAKE META LIPOATE®

Do not share medicines prescribed for you with any other person. Always take **META LIPOATE®** 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.

Directions for use:

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

IF YOU TAKE MORE META LIPOATE® THAN YOU SHOULD

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

IF YOU FORGET TO TAKE META LIPOATE®

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

POSSIBLE SIDE EFFECTS

META LIPOATE® may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **META LIPOATE®** 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/8>. By reporting side effects, you can help provide more information on the safety of **META LIPOATE®**.

STORAGE AND DISPOSING OF META LIPOATE®

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

PRESENTATION OF META LIPOATE®

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

IDENTIFICATION OF META LIPOATE®

Off-white with yellow speckles, uncoated oval tablet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

08 January 2025

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

META LIPOATE® , 60 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BEANGRIKTE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER META LIPOATE® BEVAT

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

Alfa Lipoiensuur 300 mg

Onaktiewe bestanddele: Magnesiumstearaat (groente), mikrokristallyne sellulose en silika.

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

WAT IS META LIPOATE® KAPSULES EN WAARVOOR WORD DIT GEBRUIK

META LIPOATE® is bekend vir sy antioksidante eienskappe. Hierdie formulering kan algemeen gesondheid en welstand ondersteun deur dra by tot die liggaam se antioksidante verdediging en bevorder 'n gebalanseerde metabolisme omgewing.

VOORDAT JY META LIPOATE® NEEM

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 **CHIRURGIE: META LIPOATE®** moet ten minste 2 weke voor die vermindering van bloedingsrisiko's gestaak word. **LABORATORIUMTOETSE:** Aktiewe bestanddele in: **META LIPOATE®** kan die resultate van toetse verander. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **META LIPOATE®** neem voordat jy enige laboratoriumtoetse ondergaan. gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. **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 **META LIPOATE®** 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 koorördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **META LIPOATE®** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET META LIPOATE®

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.

SWANGERSKAP EN BORSVOEDING

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

HOE OM META LIPOATE® TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **META LIPOATE®** 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:

Volwassenes Neem daaglik een (1) tablet, of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER META LIPOATE® 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 META LIPOATE® TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

META LIPOATE® kan nuwe-effekte hê.

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 inngem met trioidhormoonvlakke of behandelings, Lae bloedsuiker (hipoglukemie): Kan insulieniensitiwiteit verhoog, wat lei tot verlaagde bloedsuikervlakke, veral by diabeete As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antidiabetiese middels (bv. insulien, metformien): Kan glukoseverlagende effekte verbeter, wat die risiko van hipoglukemie verhoog, Skildkliermedikasie (bv. vereis monitering, Cisplatin (chemoterapiemiddel): Kan die doeltreffendheid van cisplatin verminder, Alkohol: Chroniese gebruik van alkohol kan ALA-verwante 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 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 **META LIPOATE®** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- Gastrointestinale probleme, metaalsmaak in die mond.

Nie alle nuwe-effekte en interaksies wat vir **META LIPOATE®** 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 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 **META LIPOATE®**.

HOE OM META LIPOATE® TE BEREË

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

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

AANBIEDING VAN META LIPOATE®

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

IDENTIFIKASIE VAN META LIPOATE®

Naaswit met geel spikkels, onbedekte ovaal tablet.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESIONELE INLIGTING

Skander QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

08 Januarie 2025

NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

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