

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

LIPO-GEN™, 90 Tablets

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

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

WHAT IS IN THIS LEAFLET

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

WHAT LIPO-GEN™ CONTAINS

Each one (1) tablet of **LIPO-GEN™** contains the following actives:

Choline (as choline bitartrate)	300 mg
Inositol (as myo-inositol)	150 mg
Betaine HCl	100 mg
L-Methionine	100 mg
Vitamin C (as ascorbic acid)	100 mg
Taurine	100 mg
Chen Pi (Citrus reticulata) [Peel 5:1 Extract standardized to 2% total bioflavonoids]	65 mg
Magnesium (as magnesium oxide)	50 mg
Artichoke (Cynara scolymus) [Leaf 10:1 Extract (containing cynarin and chlorogenic acid)]	30 mg
Vitamin B6 (as pyridoxine HCl)	10 mg
Folate (as calcium L-5-methyltetrahydrofolate)	99 µg
Vitamin B12 (as methylcobalamin)	10 µg

Inactive Ingredients: Cellulose, coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose), stearic acid (vegetable), croscarmellose sodium and silica.

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

WHAT LIPO-GEN™ IS AND WHAT IT IS USED FOR

LIPO-GEN™ 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.

BEFORE YOU TAKE LIPO-GEN™

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 **LIPO-GEN™** 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.

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 **LIPO-GEN™** 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 **LIPO-GEN™** may affect you.

TAKING OTHER MEDICINES WITH LIPO-GEN™

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 LIPO-GEN™

Do not share medicines prescribed for you with any other person. Always take **LIPO-GEN™** 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: Take two (2) tablets with food twice daily or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

IF YOU TAKE MORE LIPO-GEN™ 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 LIPO-GEN™

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

POSSIBLE SIDE EFFECTS

LIPO-GEN™ 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 (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 (Ketalar). If any of the following happens, stop using **LIPO-GEN™** 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 **LIPO-GEN™**. 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):

- Sweating, a fishy body odor, diarrhea, and vomiting.

Not all side effects and interactions reported for **LIPO-GEN™** 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 **LIPO-GEN™**.

STORAGE AND DISPOSING OF LIPO-GEN™

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 **LIPO-GEN™** if you notice visible signs of deterioration.

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

PRESENTATION OF LIPO-GEN™

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

IDENTIFICATION OF LIPO-GEN™

Tan, speckled, coated 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

19 November 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

LIPO-GEN™, 90 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER LIPO-GEN™ BEVAT

Elke een (1) tablet LIPO-GEN™ bevat die volgende aktiewe:

Cholien (as cholienbitartraat)	300 mg
Inositol (as myo-inositol)	150 mg
Betaine HCl	100 mg
L-metionien	100 mg
Vitamiën C (as askorbienisuur)	100 mg
Taurine	100 mg
Chen Pi (Citrus reticulata) [Skil 5: 1 Uittreksel gestandaardiseer tot 2% totale bioflavonoïede]	65 mg
Magnesium (as magnesiumoksied)	50 mg
Artisjok (Cynara scolymus) [Blaar 10:1 Uittreksel (bevat sinariën en chlorogeen suur)]	30 mg
Vitamiën B6 (as piridoksien HCl)	10 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	99 µg
Vitamiën B12 (as metielkobalamien)	10 µg

Onaktiewe bestanddele: Sellulose, laag (hipromellose, mediumketting triglisieriede en hidrosipropylsellulose), steariensuur (groente), kroskarmellose natrium en silika.

Hierdie produk is nie-GMO, glutenvry, suiwelvry

WAT IS LIPO-GEN™ KAPSULES EN WAARVOOR WORD DIT GEBRUIK

LIPO-GEN™ is 'n formule wat 'n unieke mengsel van lipotropiese bevat voedingstowwe gekombineer met uitgesoekte aminosure, vitamienë en 'n Eie uittreksel van kruie om gesonde lewer en spysvertering te ondersteun.

VOORDAT JY LIPO-GEN™ NEM

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 **LIPO-GEN™** 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 MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **LIPO-GEN™** die daaglikse aktiwiteit 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 **LIPO-GEN™** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET LIPO-GEN™

Komplementêre medisyne produseer 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 LIPO-GEN™ TE NEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **LIPO-GEN™** 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: Neem twee (2) tablette met kos twee keer per dag of soos aangedui deur jou gesondheidsorgpraktisyn

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER LIPO-GEN™ NEM 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 LIPO-GEN™ TE NEM

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

MOONTLIKE NUWE-EFFEKTE

LIPO-GEN™ kan nuwe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Suikersiekte, Maagresiekte, Asidose, Verharding van die are (aterosklerose), Lewersiekte, insluitend sirrose, Metilientetrahidrofolaatreduktase (MTHFR) tekort, Skisofrenie, Alkoholgebruiksversteuring, Kanker, Chroniese niersiekte, 'n metaboliese tekort genaamd "glukose-6-fosfaat dehidrogenase" (G6PD) tekort, Nier stene, Bloedingsversteurings, Hartblok, '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: Atropien, Medikasie vir diabetes (Antidiabetes dwelms), Teenuurmiddels, maagsuur (H2-blokkers, Protonpomp remmers), Estrogeen, kanker (Alkyleringsmiddels, Antitumor antibiotika), Niasien, Warfarin (Coumadin), Levothyroxine (Synthroid), Acetaminophen (Tylenol), Aspirien, Salsalate (Disalcid), Litium, hoë bloeddruk (Antihypertensiewe middels, Kalsiumkanaalblokkers), Antibiotika (Aminoglikosiedantibiotika), Antibiotika (Kinolonantibiotika), Bisfosfonate, Waterpille (Kaliumbesparende diuretika), bloedstolling (Antikoagulant / Antiplaatlet middels), Digoxin (Lanoxin), Medikasie vir diabetes (Sulfonylureas), Teenuurmiddels, Gabapentien (Neurontin), Ketamien (Ketalar). As enige van die volgende gebeur, hou op om **LIPO-GEN™** te gebruik en vertel jou dokter of gaan na die ongevallende-afdeling van 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 **LIPO-GEN™** 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):

- Sweet, 'n visagtige liggaamsreuk, diarree en braking

Nie alle nuwe-effekte en interaksies wat vir **LIPO-GEN™** 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 **LIPO-GEN™**.

HOE OM LIPO-GEN™ TE BÊRE

Hou buite bereik van kinders.

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

Beskermer 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 **LIPO-GEN™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN LIPO-GEN™

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

IDENTIFIKASIE VAN LIPO-GEN™

Bruin, gespikkelde, bedekte tablet.

REGISTRASIE NOMMER

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 REGISTRASIEHOUER

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