

SOLAL® ARGININE (L-ARGININE)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® ARGININE (L-Arginine), capsules

Read all of this leaflet carefully because it contains important information for you

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

SOLAL® ARGININE (L-Arginine) is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SOLAL® ARGININE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SOLAL® ARGININE (L-Arginine) with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT SOLAL® ARGININE (L-Arginine) CONTAINS

The active substance is:	
L-Arginine HCL	700,0 mg
providing L-Arginine	579,0 mg

The other ingredients are: Colloidal anhydrous silica, hypromellose, magnesium silicate and magnesium stearate.

WHAT SOLAL® ARGININE (L-Arginine) IS USED FOR

Category D Complementary Medicine. Discipline 34.1 Health Supplements. Amino acids SOLAL® ARGININE (L-Arginine) supports sperm count and motility. Supports reproductive health in men and women. SOLAL® ARGININE (L-Arginine) is involved in protein synthesis and may enhance exercise ability. It may help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.

BEFORE YOU TAKE SOLAL® ARGININE (L-Arginine)

Do not take SOLAL® ARGININE (L-Arginine) if you are hypersensitive (allergic) to any of the ingredients. Do not use SOLAL® ARGININE (L-Arginine) if you have had a heart attack (myocardial infarction).

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

Take special care with SOLAL® ARGININE (L-Arginine)

Consult a relevant healthcare provider:

- If your cardiovascular (heart) condition worsens.
- Prior to use if you have a renal/kidney disease or if you are following a low protein diet.
- Prior to use if you suffer from a cardiovascular disease and are attempting an increase in physical activity.
- Prior to use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners.
- Prior to use if you are pregnant or breastfeeding.

Taking SOLAL® ARGININE (L-Arginine) with food and drink

Take SOLAL® ARGININE (L-Arginine) on an empty stomach.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking SOLAL® ARGININE (L-Arginine). South Africa Safety during pregnancy and breastfeeding has not been established.

Important information about some of the ingredients of SOLAL® ARGININE (L-Arginine)

Sugar free. Suitable for vegetarians

Taking other medicines with SOLAL® ARGININE (L-Arginine)

Always tell your healthcare provider if you are taking any other medicine.

Consult your healthcare practitioner prior to use if you are taking any of the following medicine, as, theoretically, combination with SOLAL® ARGININE (L-Arginine) can potentiate their effect:

- Antidiabetic medicines such as metformin.
- Antiplateletes (medicines used for blood clotting) e.g warfarin.
- High blood pressure and/or heart failure medicines, e.g enalapril.
- Potassium sparing diuretics (water pills), e.g amiloride.
- Sildenafil, used for erectile dysfunction (difficulty in getting or maintaining an erection).

HOW TO TAKE SOLAL® ARGININE (L-Arginine)

Do not share medicines prescribed for you with any other person. Always take SOLAL® ARGININE (L-Arginine) exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is:

Adults 18 years and older:

Exercise support: Take 2 – 4 capsules twice daily, on an empty stomach.

Reproductive health support: Take 2 – 3 capsules twice daily, on an empty stomach.

Ensure to drink enough fluid before, during, and after exercise.

If you take more SOLAL® ARGININE (L-Arginine) than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of SOLAL® ARGININE (L-Arginine)

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

SOLAL® ARGININE (L-Arginine) can have side effects. Side effects may include gastrointestinal (stomach) discomfort such as diarrhoea.

Not all side effects reported for SOLAL® ARGININE (L-Arginine) are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOLAL® ARGININE (L-Arginine), please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF SOLAL® ARGININE (L-Arginine)

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package / container.

Keep the container tightly closed.

Protect from moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / bottle.

Do not use SOLAL® ARGININE (L-Arginine) if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF SOLAL® ARGININE (L-Arginine)

A white plastic container with a white plastic screw cap and a seal for protection, containing 120 capsules.

IDENTIFICATION OF SOLAL® ARGININE (L-Arginine)

A clear, SOLAL branded (black ink) capsule containing a white to off-white powder.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

PROFESSIONAL INFORMATION

For further information refer to the Professional Information of the product.

NAME AND ADDRESS OF REGISTRATION HOLDER

Ascendis Consumer Brands (Pty) Ltd

1 Carey Street

Wynberg, Gauteng 2090

South Africa

+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA

SOLAL® ARGININE (L-ARGININE)

PASIËNTINLIGTINGSBLAADJIE (Afrikaans)

SKEDULERINGSSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

SOLAL® ARGININE (L-Arginine), kapsules

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou

'n Dieët met verskeidenheid is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling sowel as geestelike en fisiese prestasies te bewerkstellig.

SOLAL® ARGININE (L-Arginine) is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nogsteeds SOLAL® ARGININE (L-Arginine) versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubljiet, dit mag dalk nodig wees om dit weer te lees.
- Moenie SOLAL® ARGININE (L-Arginine) met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

WAT SOLAL® ARGININE (L-Arginine) BEVAT

Die aktiewe bestandel is:	
L-Arginien HCL	700,0 mg
verskat L-Arginien	579,0 mg

Die ander bestanddele is: Kolloidale anhidriese silika, hipromellose, magnesiumsilikaat en magnesiumstearaat.

WAARVOOR SOLAL® ARGININE (L-Arginine) GEBRUIK WORD

Kategorie D Komplementêre Medisyne Discipline 34.1 Gesondheidsaanvulling. Aminosure SOLAL® ARGININE (L-Arginine) ondersteun spermteeling en motiliteit. Ondersteun reproduktiewe gesondheid in mans en vroue.

SOLAL® ARGININE (L-Arginine) is betrokke in proteien sintese en kan oefening vermoë verbeter.

Dit kan help om 'n matige verbetering in oefening vermoë te ondersteun in individue wat stabiele kardiovaskulêre siektes het.

VOORDAT SOLAL® ARGININE (L-Arginine) GEBRUIK WORD

Moenie SOLAL® ARGININE (L-Arginine) gebruik indien jy hipersensitief (allergies) is vir enige van die bestanddele nie. Moet nie SOLAL® ARGININE (L-Arginine) gebruik indien jy 'n hartaanval (miokardiale infarksie) gehad het nie. Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Neem spesiale sorg met SOLAL® ARGININE (L-Arginine)

Raadpleeg 'n toepaslike gesondheidsorgverskaffer:

- Indien jou kardiovaskulêre (hart) kondisie versleg.
- Voor gebruik indien jy aan nier siektes ly of 'n lae proteïen dieet volg.
- Voor gebruik indien jy aan kardiovaskulêre siektes ly en probeer om jou fisiese aktiwiteit te verhoog.
- Voor gebruik indien jy medikasie neem vir kardiovaskulêre siektes, erketiele disfunksie, en/of bloedverdunners.
- Voor gebruik as jy swanger is of borsvoed.

Neem van SOLAL® ARGININE (L-Arginine) met voedsel en vloeistof

Neem SOLAL® ARGININE (L-Arginine) op 'n leë maag.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat jy SOLAL® ARGININE (L-Arginine) gebruik. Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Belangrike inligting in verband met sommige van die bestanddele in SOLAL® ARGININE (L-Arginine)

Suikervry

Geskik vir vegetariërs

As jy ander medisyne saam met SOLAL® ARGININE (L-Arginine) neem

Siel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne gebruik.

Raadpleeg jou gesondheidsorgpraktisyn voor gebruik as jy enige van die volgende medisyne neem aangesien die kombinasie met SOLAL® ARGININE (L-Arginine), teoreties, hulle effekte kan potensieer.

- Antidiabetiese medisyne soos metformien.
- Antiplaattie-middels (medisyne wat gebruik word vir bloedklonting) bv. warfarin.
- Hoë bloeddruk en/of hartversaking medisyne bv. enalapril.
- Kaliumsparende diuretika (waterpille) bv. amiloried.
- Sildenafil wat gebruik word vir erektele distonksie (onvermoë om 'n ereksie te kry of te onderhou).

HOE OM SO SOLAL® ARGININE (L-Arginine) TE NEEM

Moenie jou medisyne met enige iemand anders deel nie. Neem SOLAL® ARGININE (L-Arginine) altyd presies soos aanbeveel. Bevestig met jou dokter of apteker indien jy onseker is.

Die normale dosering is:

Volwassenes 18 jaar en ouer: Oefening ondersteuning: Neem 2 – 4

kapsules twekeer daagliks op 'n leë maag.

Ondersteuning van reproduktiewe gesondheid: Neem 2 – 3 kapsules twekeer daagliks, op 'n leë maag.

Maak seker dat jy genoeg vloeistof drink voor, tydens en na oefening.

Indien jy meer SOLAL® ARGININE (L-Arginine) neem as wat jy behoort

Indien oordosering vermoed word, raadpleeg onmiddellik jou dokter of apteker. Indien geneen beskikbaar is nie, kontak die naaste hospitaal of gilbeheersentrum.

Indien jy vergeet het om SOLAL® ARGININE (L-Arginine) te neem

Moenie 'n dubbele dosis neem om vir oorgeslane dosisse te vergoed nie.

MOONTLIKE NEWE-EFFEKTE

SOLAL® ARGININE (L-Arginine) kan moontlik newe-effekte veroorsaak. Newe-effekte mag insluit gastrointestinale (maag) ongemak soos diarree.

Nie alle newe-effekte wat vir SOLAL® ARGININE (L-Arginine) aangemeld is word in hierdie voubljiet genoem nie. Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind terwyl jy SOLAL® ARGININE (L-Arginine) gebruik, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg.

Indien jy enige newe-effekte waarneem wat nie in hierdie voubljiet genoem word nie, moet jy jou dokter of apteker daarvan vertel.

BERGING EN WEGDOEN VAN SOLAL® ARGININE (L-Arginine)

Bewaar alle medikasie buite bereik van kinders. Bewaar teen of benede 25 °C.

Bewaar in die oorspronklike houer.

Maak die houer dig toe.

Beskerem teen vog.

Moenie die produk in die badkamer bewaar nie.

Moenie na die vervaldatum wat op die etiket / bottel aangedui is, gebruik nie.

Moenie SOLAL® ARGININE (L-Arginine) gebruik indien jy enige sigbare tekens van produkafbraak opmerk nie.

Besorg enige ongebruikte medisyne terug aan jou apteker. Moenie van ongebruikte medisyne ontslae raak in dreine of rioolstelsels nie (bv. toilette).

AANBIEDING VAN SOLAL® ARGININE (L-Arginine)

'n Wit plastiekhouer met 'n wit plastiek skroeldeksel en 'n seël vir beskerming wat 120 kapsules bevat.

IDENTIFIKASIE VAN SOLAL® ARGININE (L-Arginine)

'n Deursigtige, SOLAL gemerkte (swart ink) kapsule wat 'n wit tot roomwit poeier bevat.

REGISTRASIEONOMMER

TBA

DATUM VAN REGISTRASIE

TBA

PROFESIONELE INLIGTING

Verwys na die voubljiet met Professionele Inligting vir meer inligting.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Ascendis Consumer Brands (Pty) Ltd

1 Carey Street

Wynberg, Gauteng 2090

South Africa

+27 11 036 9420

DATUM VAN PUBLIKASIE VAN DIE PROFESIONELE INLIGTING

TBA

905M311/00

SOLAL® ARGININE (L-ARGININE)

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® ARGININE (L-Arginine), capsules

COMPOSITION

Each capsule contains:	
L-Arginine HCL	700,0 mg
providing L-Arginine	579,0 mg

Inactive ingredients: Colloidal anhydrous silica, hypromellose, magnesium silicate and magnesium stearate. Sugar free. Suitable for vegetarians.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine Discipline 34.1 Health Supplements. Amino acids

PHARMACOLOGICAL ACTION

L-Arginine is a substrate for the enzyme nitric oxide (NO) synthase. NO increases the relaxation of urinary tract smooth muscle and is involved in erectile function.

L-arginine has been used to help with infertility. Research suggests that NO from L-arginine may stimulate motility and metabolism of sperm from asthenospermic patients. L-arginine supplementation affects NO production and improves uterine blood flow and endometrial thickness in females.

INDICATIONS

SOLAL® ARGININE (L-Arginine) supports sperm count and motility. Supports reproductive health in men and women. SOLAL® ARGININE (L-Arginine) is involved in protein synthesis and may enhance exercise ability. It may help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.

CONTRAINDICATIONS

Hypersensitive (allergic) to any of the ingredients of SOLAL® ARGININE (L-Arginine).

Individuals who have had a heart attack/myocardial infarction.

WARNINGS and SPECIAL PRECAUTIONS

Exercise caution when used in individuals:

- With worsening cardiovascular condition.
- With renal/kidney disease or following a low protein diet.
- Suffering from a cardiovascular disease and are attempting an increase in physical activity.
- Taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners.
- Who are pregnant or lactating.

Theoretically, L-Arginine, as in SOLAL® ARGININE (L-Arginine), might interfere with blood pressure control during and after surgical procedures due to its ability to lower blood pressure. Advise patients to discontinue SOLAL® ARGININE (L-Arginine) at least 2 weeks before elective surgical procedures.

Ensure intake of enough fluid before, during, and after exercise. This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

INTERACTIONS

Theoretically, L-Arginine, as in SOLAL® ARGININE (L-Arginine), can potentiate effects of the following medicines: antidiabetic (e.g metformin), antihypertensives and ACE inhibitors (e.g enalapril), antiplatelets (e.g warfarin), sildenafil and potassium-sparing diuretics (e.g amiloride).

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults 18 years and older:

Exercise support: Take 2 – 4 capsules twice daily, on an empty stomach.

Reproductive health support: Take 2 – 3 capsules twice daily, on an empty stomach.

Ensure to drink enough fluid before, during, and after exercise.

SIDE EFFECTS

SOLAL® ARGININE (L-Arginine) may cause gastrointestinal discomfort (such as diarrhoea).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

IDENTIFICATION

A clear, SOLAL branded (black ink) capsule containing a white to off-white powder.

PRESENTATION

A white plastic container with a white plastic screw cap and a seal for protection, containing 120 capsules.

STORAGE INSTRUCTIONS

Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

TBA

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NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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