

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### ARGININE PLUS™, 120 Tablets

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

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

#### WHAT IS IN THIS LEAFLET

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

#### WHAT ARGININE PLUS™ CONTAINS

Each one (1) tablet of **ARGININE PLUS™** contains the following actives:

L-Arginine	1,5 g
Glycine	10 mg
Folate (as Calcium L-5-methyltetrahydrofolate)	400 µg

**Inactive Ingredients:** Calcium silicate, cellulose, coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose), croscarmellose sodium, microcrystalline cellulose, stearic acid (vegetable) and silica.

**This product is suitable for Vegetarians, non-GMO (Sugar free)**

#### WHAT ARGININE PLUS™ IS AND WHAT IT IS USED FOR

**ARGININE PLUS™** delivers high quality L-Arginine with folate to support healthy blood flow, homocysteine levels, and overall cardiovascular health. Providing L-5-methyltetrahydrofolate helps to ensure improved folate nutrition, even in those with genetic variations in folate metabolism.

#### BEFORE YOU TAKE ARGININE PLUS™

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **ARGININE PLUS™** 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:** **ARGININE PLUS™** might slow blood clotting. It might cause extra bleeding during and after surgery. Stop using **ARGININE PLUS™** at least 2 weeks before a scheduled surgery.

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

#### PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has 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 **ARGININE PLUS™** 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 **ARGININE PLUS™** may affect you.

#### TAKING OTHER MEDICINES WITH ARGININE PLUS™

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 ARGININE PLUS™

Do not share medicines prescribed for you with any other person. Always take **ARGININE PLUS™** 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.

**Caution: Consult your healthcare practitioner before use.**

#### Directions for use:

**Adults:** Take two (2) tablets daily or as advised by your healthcare practitioner.

**Do not take more than the recommended dose.**

#### IF YOU TAKE MORE ARGININE PLUS™ 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 ARGININE PLUS™

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

#### POSSIBLE SIDE EFFECTS

**ARGININE PLUS™** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Guanidinoacetate methyltransferase deficiency (GAMT), Recent heart attack, Kidney disease, Cancer, Seizure disorder, Vitamin B12 deficiency. If you are taking the following medication, please consult with your healthcare practitioner before taking: Antihypertensive drugs, Sildenafil (Viagra), high blood pressure (ACE inhibitors), high blood pressure (Angiotensin receptor blockers (ARBs)), slow blood clotting (Anticoagulant / Antiplatelet drugs), Medications for diabetes (Antidiabetes drugs), Water pills (Potassium-sparing diuretics), Testosterone. If any of the following happens, stop using **ARGININE PLUS™** 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 **ARGININE PLUS™**. 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):

- stomach pain, bloating, diarrhea.

Not all side effects and interactions reported for **ARGININE PLUS™** 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 **ARGININE PLUS™**.

#### STORAGE AND DISPOSING OF ARGININE PLUS™

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 **ARGININE PLUS™** if you notice visible signs of deterioration.

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

#### PRESENTATION OF ARGININE PLUS™

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### IDENTIFICATION OF ARGININE PLUS™

White oblong 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 December 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd

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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

## ARGININE PLUS™, 120 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WAT ARGININE PLUS™ BEVAT

Elke een (1) tablette **ARGININE PLUS™** bevat die volgende aktiewe:

L-arginien	1,5 gram
Glisien	10 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	400 µg

**Onaktiewe bestanddele:** Kalsiumsulfaat, sellulose, laag (hipromellose, mediumketting trigliseriede, en hidrokispropylselulose), croscarmellose, croscarmellose, natrium, mikrokristallyne sellulose, steariensuur (groente) en silika.

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

WAT IS ARGININE PLUS™ KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**ARGININE PLUS™** lewer hoë kwaliteit L-arginien met folaat om gesonde bloedvloei, homosisteïenvlakke en algemene kardiovaskulêre gesondheid te ondersteun. Die verskaffing van L-5-metiltetrahidrofolaat help om verbeterde folaatvoeding te verseker, selfs in diene wat genetiese variasies in folaatmetabolisme.

VOORDAT JY ARGININE PLUS™ NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **ARGININE PLUS™** 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: ARGININE PLUS™** kan bloedstolling vertraag. Dit kan ekstra bloeding tydens en na die operasie veroorsaak. Hou op om **ARGININE PLUS™** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik.

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, raadpleeg u gesondheidsorgpraktisyn vir gebruik. 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 **ARGININE PLUS™** 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, vlug, sel, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **ARGININE PLUS™** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET ARGININE PLUS™

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 ARGININE PLUS™ TE NEEM

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

**Aanwysings vir gebruik:**

**Volwassenes:** Neem twee (2) tablette daaglik of soos aanbeveel deur jou gesondheidspraktisyn.

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

**AS JY MEER ARGININE PLUS™ 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 ARGININE PLUS™ TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

**ARGININE PLUS™** kan nuwe-effekte hê.

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Guanidinoasetaat-metieltransferase-tekort (GAMT), Onlangse hartaanval, Niersiekte, Kanker, Beslagleggingsversteuring, Vitamien B12-tekort. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Antihypertensiewe middels, Sildenafil (Viagra), hoë bloeddruk (ACE-remmers), hoë bloeddruk (Angiotensienreseptorblokkers (ARB's)), stadige bloedstolling (Antikoagulant / Antiplaatjie-middels), medisyne vir diabetes (Antidiabetes-middels), Waterpille (Kaliumbesparende diuretika), Testosteron. As enige van die volgende gebeur, hou op om **ARGININE PLUS™** 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), erge duiseligheid, probleme met asemhaling;

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

- maagpyn, opgeblasenheid, diarree

Nie alle nuwe-effekte en interaksies wat vir **ARGININE PLUS™** 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 **ARGININE PLUS™**.

HOE OM ARGININE PLUS™ TE BÊRÊ

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerk 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 **ARGININE PLUS™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN ARGININE PLUS™

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêel, peuterkrimpseël, spons en silikagelakke.

IDENTIFIKASIE VAN ARGININE PLUS™

Wit langwerpige bedekte tablet.

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 Desember 2024

NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

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