

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

ARGININE PLUS™, 120 Tablets

COMPOSITION

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)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

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.

Ingredients	Uses for ingredient
L-Arginine	L-arginine is converted in the body into a chemical called nitric oxide. Nitric oxide causes blood vessels to open wider for improved blood flow.
Glycine	Glycine is precursor for a variety of important metabolites such as glutathione, porphyrins, purines, haem, and creatine.
Folate (as Calcium L-5-methyltetrahydrofolate)	It enables the conversion of homocysteine to methionine and the production of serotonin and melatonin.

CONTRA INDICATIONS:

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

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Guaninoacetate 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 professional before taking: oral diabetes medicine, medicines that reduce stomach acid. Anthypertensive 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

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.

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.

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 two (2) tablets daily or as advised by your healthcare practitioner.

Do not take more than the recommended dose.

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.

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.

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

IDENTIFICATION

White oblong coated tablet.

PRESENTATION

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

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

34.12 Meervoudige Bestandeel Formulasie

HANDELSNAAM EN DOSEERVORM,

ARGININE PLUS™, 120 Tablette

SAMESTELING

Elke (1) tablet ARGININE PLUS™ bevat die volgende aktiewe stowwe:

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

Onaktiewe bestanddele: Askorbienuur (antioksidant), mediumketting trigliseriede, Kalsiumsilikaat, sellulose, laag (hipromellose, mediumketting trigliseriede, en hidrokispropylselleulose), croscarmellose, croscarmellose, natrium, mikrokristallyne sellulose, steariensuur (groente) en silika.

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

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

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

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **ARGININE PLUS™** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nowe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- maagpyn, opgeblasenheid, diarree
- Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **ARGININE PLUS™** 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.

INTERAKSIE

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**)

DOOSIS EN AANWYSINGS VIR GEBRUIK

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

Moenie meer as die aanbevole dosis neem 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 newe-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 newe-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.

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

IDENTIFIKASIE

Wit langwerpige bedekte tablet.

AANBIDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseël, 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

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

Bestanddele	Gebruik vir bestanddeel
L-arginien	L-arginien word in die liggaam omgeskakel in 'n chemikalie genaamd stikstofoksied. Stikstofoksied veroorsaak dat bloedvate wyer oopgaan vir verbeterde bloedvloei.
Glisien	Glisien is voorloper vir 'n verskeidenheid belangrike metaboliete soos glutathion, porfyriene, puriene, haem en kreatien.
Folaat (as kalsium L-5-metietletetrahydrofolaat)	Dit maak die omskakeling van homosisteïen na metionien en die produksie van serotonien en melatonien moontlik.

KONTRA-INDIKASIE:

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.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Guanidinoasetaat-metieltransferasietekort (GAMT), Onlangse hartaanval, Niersiekte, Kanker, Beslagleggingsversteuring, Vitamien B12-tekort. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn 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 ongevallenafdeling by jou naaste hospitaal:

- Allergiese reaksie-uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;