

PROFESSIONAL INFORMATION**Complementary Medicine: Amino Acid (Health Supplement)**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.
Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0**1. NAME OF THE MEDICINE****BIOGEN L-ARGININE PERFORMANCE (capsules)****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Arginine Hydrochloride Providing L-arginine (elemental)	600 mg 499 mg
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Sugar Free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Size 00 white to off white veggie capsule.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

L-arginine is an amino acid involved in muscle protein synthesis, that may improve the exercise capacity in individuals.

BIOGEN L-ARGININE PERFORMANCE is indicated in adults 18 years and older.

4.2 Posology and method of administration

Adults:

Take four (4) capsules daily.

Additional information on special populations:

Elders:

No specific studies have been performed in the elderly, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, elderly patients.

Children and adolescents:

BIOGEN L-ARGININE PERFORMANCE is not recommended for use in children and adolescents below the age of 18 years, as safety and efficacy have not been established.

4.3 Contraindications

BIOGEN L-ARGININE PERFORMANCE must not be used:

In patients who have had a heart attack/myocardial infarction.

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- L-arginine can cause an allergic response or aggravate airway inflammation. L-arginine might exacerbate allergies. Individuals who are prone to allergies (atopy) or asthma should use L-arginine with caution.
- Theoretically, L-arginine might worsen hypotension by increasing nitric oxide, which in turn causes vasodilation.
- There is concern that L-arginine might worsen outcomes, by increasing reactive oxygen species and homocysteine, when taken by patients following a myocardial infarction. L-arginine might also increase the activity of an isoform of nitric oxide synthetase that is induced by atherosclerotic disease.
- L-arginine has caused hyperkalaemia, occasionally with fatal cardiac arrhythmia, in patients with renal insufficiency or failure.
- L-arginine-containing infusions can lead to a hyper-dynamic circulatory state related to an elevation of the plasma level of nitric oxide.
- Patients with guanidinoacetate methyltransferase deficiency require dietary restriction of arginine.
- L-arginine may exacerbate the herpes virus; as preliminary evidence suggests that L-arginine may be necessary for viral replication.
- L-arginine might affect blood pressure and might interfere with blood pressure control during and after surgical procedures. Patients should discontinue use of L-arginine at least two weeks before elective surgical procedures.

4.5 Interaction with other medicines and other forms of interaction

- Combining the use of L-arginine with some antihypertensive drugs, especially angiotensin-converting enzyme (ACE) inhibitors, seems to have additive vasodilating and blood pressure-lowering effects. Theoretically, the concomitant use may increase the risk of blood pressure becoming too low. Furthermore, ACE inhibitors can increase potassium levels. The use of L-arginine has been associated with hyperkalaemia in some patients. Theoretically, concomitant use of ACE inhibitors with L-arginine increases the risk of hyperkalaemia.
- L-arginine increases nitric oxide, which causes vasodilation. Combining L-arginine with angiotensin receptor blockers (ARBs) seems to increase L-arginine-induced vasodilation. This may increase the risk of blood pressure becoming too low. Furthermore, ARBs can increase potassium levels. The use of L-arginine has been associated with hyperkalaemia in some patients. Theoretically, concomitant use of ACE inhibitors with L-arginine increases the risk of hyperkalaemia.
- Preliminary evidence suggests that L-arginine infusions reduce platelet aggregation in humans. The concomitant use of L-arginine with anticoagulant and antiplatelet drugs might have additive effects and increase the risk of bleeding.
- Preliminary research in humans suggests that L-arginine decreases blood glucose levels in patients with type 2 diabetes. The concomitant use might require dosing adjustment of antidiabetes drugs.
- Clinical evidence shows that L-arginine can reduce blood pressure in some individuals with hypertension, as L-arginine increases nitric oxide, which causes vasodilation. Furthermore, combining L-arginine with some antidiabetic drugs seems to have additive vasodilating and blood pressure-lowering effects. Theoretically, concomitant use of L-arginine and antihypertensive drugs may increase the risk of blood pressure becoming too low.
- Potassium-sparing diuretics can increase potassium levels. The use of L-arginine has been associated with hyperkalaemia in some patients. The concomitant use of potassium-sparing diuretics with L-arginine may increase the risk of hyperkalaemia.
- Concomitant use of xylitol and L-arginine can reduce the glucagon response to L-arginine.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established as there is insufficient reliable data available.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain L-ARGININE PERFORMANCE does not adversely affect their performance.

4.8 Undesirable effects**Gastrointestinal:**

Frequent: nausea, abdominal pain, diarrhoea, dyspepsia, bloating.

Less frequent: acute pancreatitis.

Pulmonary/Respiratory:

Frequent: allergic response, airway inflammation and exacerbation of airway inflammation in asthma.

Dermatologic:

Frequent: rash, hives.

Musculoskeletal:

Less frequent: asthenia.

Neurologic/CNS:

Frequent: headache and vertigo.

Cardiovascular:

Less frequent: palpitations.

Oncologic:

Less frequent: stimulated tumour protein synthesis in breast cancer patients.

Renal:

Less frequent: gout.

Other:

Less frequent: delayed menses, night sweats, flushing.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. In addition, overdose has resulted in symptoms including vomiting, respiratory distress, and metabolic acidosis. Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Category D 34.1: Complementary Medicine: Amino Acids (Health Supplement)
L-arginine is an amino acid involved in muscle protein synthesis, that may improve the exercise capacity in individuals.

5.2 Pharmacokinetic properties

L-arginine has an oral bioavailability of 68%. The degradation of arginine produces nitric oxide, polyamines, proline, glutamate, creatine and agmatine. Arginase hydrolyses arginine into urea and ornithine. L-arginine is broken down into nitric oxide and L-citrulline. L-citrulline can be converted again into arginine.

L-arginine has an elimination half-life of approximately 80 minutes.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Sugar Free

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Protect from moisture and store at or below 25 °C.

Keep capsules in original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

White PET bottle with white PET screw cap.

Pack-size: 120 veggie capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

JOB: BPS_L-Arginine_Pi/PIL	SIZE: 210mm x 408mm								
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PATIENT INFORMATION LEAFLETSCHEDULING STATUS: **[S0]****BIOGEN L-ARGININE PERFORMANCE (capsules)**Arginine Hydrochloride
Providing L-arginine (elemental)600 mg
499 mg

Sugar Free

Complementary Medicine: Amino Acid (Health Supplement)This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.
Health supplements are intended only to complement health or supplement the diet.**Read all of this leaflet carefully because it contains important information for you.**

BIOGEN L-ARGININE PERFORMANCE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use BIOGEN L-ARGININE PERFORMANCE carefully to get the best results from it.

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

What is in this leaflet

- What BIOGEN L-ARGININE PERFORMANCE is and what it is used for.
- What you need to know before you use BIOGEN L-ARGININE PERFORMANCE.
- How to use BIOGEN L-ARGININE PERFORMANCE.
- Possible side effects.
- How to store BIOGEN L-ARGININE PERFORMANCE.
- Contents of the pack and other information.

1. What BIOGEN L-ARGININE PERFORMANCE is and what it is used for

BIOGEN L-ARGININE PERFORMANCE is a source of L-arginine, which is an amino acid involved in muscle protein synthesis, that may improve the exercise capacity in individuals.

2. What you need to know before you use BIOGEN L-ARGININE PERFORMANCE**Do not use BIOGEN L-ARGININE PERFORMANCE:**

- Hypersensitivity to the active substances or to any of the inactive ingredients listed in section 6.1.
- If you have had a heart attack/myocardial infarction.

Warnings and precautions

Special care should be taken with BIOGEN L-ARGININE PERFORMANCE:

- If you are prone to allergies or asthma.
- If you have low blood pressure.
- If you suffer from cirrhosis, guanidinoacetate methyltransferase deficiency, herpes, or kidney disease.
- Stop taking L-arginine at least two weeks before a scheduled surgery, as it may interfere with blood pressure control during and after surgery.

Consult with a healthcare practitioner if:

- Your cardiovascular condition worsens.
- If you have a renal/kidney disease or if you are following a low protein diet.
- You suffer from a cardiovascular disease and are attempting an increase in physical activity.
- If you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners.

Children and adolescents

Do not give BIOGEN L-ARGININE PERFORMANCE to children and adolescents below the age of 18 years, as safety and efficacy have not been established.

Other medicines and BIOGEN L-ARGININE PERFORMANCE

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

- L-arginine seems to decrease blood pressure. Avoid taking L-arginine with medication and supplements that decrease blood pressure as it might cause your blood pressure to go too low.
- Avoid taking L-arginine if you are taking ACE inhibitors for high blood pressure, or antihypertensive medications, as it may cause your blood pressure to go too low. ACE inhibitors can increase potassium levels, and L-arginine may also increase potassium levels, thus the concomitant use of ACE inhibitors and L-arginine may cause potassium levels to become too high.
- L-arginine increases blood flow. Taking L-arginine concomitantly with medications that increase blood flow to the heart (nitrates) might increase the chance of dizziness and light-headedness.
- L-arginine seems to decrease blood sugar levels in people with diabetes. Taking L-arginine along with diabetes medications might cause your blood sugar to go too low. Monitor your blood sugar levels closely as your dose of diabetes medication might need to be changed.
- L-arginine can slow blood clotting, and taking it along with medications that also slow blood clotting can increase your chance of bruising and bleeding.
- L-arginine can increase potassium levels in the body. Potassium-sparing diuretics may also increase potassium in the body. The concomitant use of L-arginine and potassium sparing diuretics should be avoided as it may result in potassium levels becoming too high in the body.

Food and drink with BIOGEN L-ARGININE PERFORMANCE

Using L-arginine along with xylitol can keep L-arginine from stimulating the pancreas to release glucagon.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using BIOGEN L-ARGININE PERFORMANCE, as safety and efficacy have not been established.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN L-ARGININE PERFORMANCE does not adversely affect their performance.

3. How to use BIOGEN L-ARGININE PERFORMANCE

Do not share medicines prescribed to you with any other person.

Always use BIOGEN L-ARGININE PERFORMANCE exactly as described in this leaflet or as your healthcare practitioner has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Take four (4) capsules daily or as recommended by your healthcare practitioner.

Additional information on special populations:**Elders:**

No specific studies have been performed in the elderly, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, elderly patients.

Children and adolescents:

BIOGEN L-ARGININE PERFORMANCE is not recommended for use in children and adolescents below the age of 18 years, as safety and efficacy have not been established.

4. Possible side effects

BIOGEN L-ARGININE PERFORMANCE can have side effects.

Not all side effects reported for BIOGEN L-ARGININE PERFORMANCE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN L-ARGININE PERFORMANCE, please consult your healthcare practitioner for advice.

If any of the following happens, stop using BIOGEN L-ARGININE PERFORMANCE and tell your doctor immediately or go to the casualty department at your nearest hospital:

Gastrointestinal:

Frequent: nausea, abdominal pain, diarrhoea, dyspepsia, bloating.

Less frequent: acute pancreatitis.

Pulmonary/Respiratory:

Frequent: allergic response, airway inflammation and exacerbation of airway inflammation in asthma.

Dermatologic:

Frequent: rash, hives.

Musculoskeletal:

Less frequent: asthenia.

Neurologic/CNS:

Frequent: headache and vertigo.

Cardiovascular:

Less frequent: palpitations.

Oncologic:

Less frequent: stimulated tumour protein synthesis in breast cancer patients.

Renal:

Less frequent: gout.

Other:

Less frequent: delayed menses, night sweats, hot flushes.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions 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 BIOGEN L-ARGININE PERFORMANCE.

5. How to store BIOGEN L-ARGININE PERFORMANCE

- Store all medicine out of reach of children.
- Store in a cool, dry place at or below 25 °C.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BIOGEN L-ARGININE PERFORMANCE contains**

Each capsule contains:

Arginine hydrochloride
Providing L-arginine (elemental) 600 mg
499 mg

Sugar Free

What BIOGEN L-ARGININE PERFORMANCE looks like and contents of the pack

White PET bottle with white PET screw cap.

Pack-size: 120 capsules.

Holder of Certificate of Registration

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration Number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: **[S0]****BIOGEN L-ARGININE PERFORMANCE (kapsules)**Argininhydrochloride
Waarvan L-arginien (elementaal)600 mg
499 mg

Suikervry

Anvullende Medisyne: Aminosure (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Les hierdie inligtingsblad noukeurig deur want dit het belangrike inligting.

BIOGEN L-ARGININE PERFORMANCE is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. U moet egter steeds BIOGEN L-ARGININE PERFORMANCE versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie BIOGEN L-ARGININE PERFORMANCE met enige ander persoon deel nie.
- Maak gebruik van BIOGEN L-ARGININE PERFORMANCE in afwyse van gesondheidsopraktisyne wat advies nodig het.

Wat is in hierdie pamphlet

- Wat is BIOGEN L-ARGININE PERFORMANCE en waaroor dit gebruik word.
- Wat u moet weet voor dat u BIOGEN L-ARGININE PERFORMANCE gebruik.
- Hoe om BIOGEN L-ARGININE PERFORMANCE te gebruik.
- Moenie BIOGEN L-ARGININE PERFORMANCE gebruik.

1. Wat is BIOGEN L-ARGININE PERFORMANCE en waaroor dit gebruik word

BIOGEN L-ARGININE PERFORMANCE is 'n bron van L-arginine, wat is 'n aminosuur betrokke by spierproteïnsintese wat die oefervermoë van individue kan verber.

2. Wat u moet weet voordat u BIOGEN L-ARGININE PERFORMANCE gebruik**Moenie BIOGEN L-ARGININE PERFORMANCE neem:**

- Hipersensitiviteit teenoor die aktiewe bestanddele of enige van die ander bestanddele gelyes in afdeling 6.1.
- Indien u 'n hartaanval/myokardiale infarkt gehad het.

Waarskuwings en voorborgmaatreës

Wees versigtig met BIOGEN L-ARGININE PERFORMANCE:

- Indien u geneig is tot allergieë of astma.
- Indien u lae bloeddruk het.
- Indien u aan sirose, guanidinoacetate-metyltransferasetekort, herpes of niersiekte ly.
- Hou op om L-arginien minstens twee weke voor 'n geskeduleerde operasie te neem, aangesien dit met bloeddrukbehoer tydens en na die operasie kan beïnvloed.

Raadpleeg 'n gesondheidsopraktisyn:

- Indien u kardiovaskuläre toestand vererger.
- Indien u lae bloeddruk.
- Indien u 'n niersieke het, of as u 'n lae proteïne dieet volg.
- Indien u ly aan 'n kardiovaskuläre siekte en probeer om u fisiese aktiwiteit te verhoog.

Kinders en adolescentse

Moenie BIOGEN L-ARGININE PERFORMANCE aan kinders en adolescentse onder die ouerdom van 18 jaar gee nie, aangesien die veiligheid en doeltreffendheid hiervan nie bepaal is nie.

Die neem van ander medisyne saam met BIOGEN L-ARGININE PERFORMANCE

Lig altyd vir u gesondheidsopraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in).

- Blyk dat L-arginien bloeddruk kan verlaag. Vermind die gebruik van L-arginien wat medisyne en aanvullings wat bloeddruk verlaag, aangesien dit moontlik kan veroorsaak dat bloeddruk te laag word.

• Vermy die gebruik van L-arginien as u ACE-remmers neem vir hoë bloeddruk, of antihypertensieve medikasie neem, want dit kan moontlik daartoe lei dat u bloeddruk te laag word. ACE-remmers kan kaliumvlakte verhoog, en L-arginien kan ook kaliumvlakte verhoog, die gegangende gebruik van ACE-remmers en L-arginien kan veroorsaak dat kaliumvlakte te hoog word.

• L-arginien verhoog bloedvloei. Die gelyktydige gebruik van L-arginien met medisyne wat bloedvloei na die hart verhoog (nitrate), kan die kans vir duiseligheid en lighoofdigheid verhoog.

• L-arginien blyk om bloedsuikervlakte by mense met diabetes te verlaag. As u L-arginien saam met medisyne vir diabetes neem, kan u bloedsuiker te laag wees. Monitor u bloedsuikervlakte noukeurig, aangesien a dosis diabetes medikasie moontlik aangespas moet word.

• L-arginien kan bloedstolling vertraag, en as dit saam met medisyne wat ook bloedstolling vertraag geneem word, kan u kans vir knieplekke en bloeding verhoog wees.

• L-arginien kan kaliumvlakte in die liggaam verhoog. Kaliumsparende diureтика kan ook kalium in die liggaam verhoog. Die gelyktydige gebruik van L-arginien en kaliumsparende diureтика moet vermy word, aangesien dit daar toe kan lei dat kaliumvlakte te hoog in die liggaam word.

Die neem van kos, drank en alcohol met BIOGEN L-ARGININE PERFORMANCE

As u L-arginien en xylitol gebruik, kan dit voorkom dat L-arginien die pankreas stimuleer om glukagon vry te stel.

Swangerskap, borsvoeding en vrugbaardheid

As u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apoteker of ander gesondheidsopraktisyn voordat u BIOGEN L-ARGININE PERFORMANCE gebruik, aangesien die veiligheid en doeltreffendheid hiervan nie bepaal is nie.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voor dat hulle bestuur van masjinerie gebruik, totdat hulle redelik seker is dat BIOGEN L-ARGININE PERFORMANCE nie huw werkverrigting nadruk beïnvloed.

3. Hoe om BIOGEN L-ARGININE PERFORMANCE te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Gebruik BIOGEN L-ARGININE PERFORMANCE presies soos aanbeveel in hierdie pamphlet, of soos aanbeveel deur u gesondheidsopraktisyn. Raadpleeg u dokter of apoteker indien u nie seker is nie.

Volvassenes:

Neem vier (4) kapsules daagliks, of soos aanbeveel deur u gesondheidsopraktisyn.

Additionele inligting vir spesiale populasies:**Bejaarde:**

Geen spesifieke studies is op bejaarde uitgevoer nie, maar volgens kliniese ondervinding is dosisaanpassing nie nodig by die behandeling van andersins gesonde, ouer pasiënte nie.

Kinders en adolescentse:

B