

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE BIOGEN PURE L-CITRULLINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4,80 g dosage contains:

L-Citrulline-DL-Malate 2:1 (providing 3,00 g L-Citrulline) 1,00 g

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

POWDER

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN PURE L-CITRULLINE, a source of an amino acid involved in muscle protein synthesis. Supports an increase in athletic performance in high-intensity anaerobic exercise with short rest period.

4.2 Posology and method of administration

Posology

Adults (18 years & older): Use as directed by a healthcare provider / sports advisor, or mix ±1 heaped measuring spoon (4,80 g) with your favorite sports drink and take it before your workout session. On non-training days, consume it first thing in the morning. Do not exceed 2 dosages (9,6 g) per day.

Paediatric population

The safety and efficacy of BIOGEN L-CITRULLINE has not been established in children under the age of 18 years.

Method of administration

For oral use.

Swallow the capsules whole.

Do not exceed 9,6 g L-Citrulline-DL-Malate 2:1 or 6 g L-Citrulline per day.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Consult a relevant health care provider for use beyond 12 weeks and before long-term use.
- Insufficient reliable information available for use during pregnancy and lactation; avoid using (Refer section 4.6).

Paediatric population

Not suitable for children below the age of 18 years unless under the direct supervision of a healthcare provider.

4.5 Interactions with other medicines and other forms of interactions

None known.

4.6 Fertility, pregnancy, and lactation

Safety in fertility, pregnancy and lactation has not been established (refer to section 4.4).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

BIOGEN L-CITRULLINE is generally well tolerated.

Gastrointestinal disorders: *Frequency unknown:* gastrointestinal intolerance, stomach discomfort, and heartburn.

Genitourinary: *Frequency unknown:* pulmonary hypertension with increased urinary frequency and edema.

Pulmonary / Respiratory: *Frequency unknown:* pulmonary hypertension with increased cough.

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 providers 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 overdose, undesirable effects as listed in 4.8 can be precipitated and / or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: D 34.1 Amino acids.

Complementary Medicine: Health Supplement

5.2 Pharmacokinetic properties

General introduction:

- L-Citrulline:* a source of an amino acid involved in muscle protein synthesis. Supports an increase in athletic performance in high-intensity anaerobic exercise with short rest period.

General characteristics:

Absorption:

- L-citrulline:* Levels are increased 10-fold after a 2 gram dose and 100-fold after a 15 gram dose, but return to baseline within 5 to 8 hours after the dose.

Metabolism:

- Beta-alanine:* Carnosine (beta-alanyl-L-histidine) is synthesized from beta-alanine and L-histidine in muscles and cells of the CNS by the enzyme carnosine synthetase.

Excretion:

- L-citrulline:* Less than 5% of oral doses of L-citrulline is excreted unchanged in the urine.

5.3 Preclinical safety data

No pre-clinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf Life

24 Months / 2 Years.

6.4 Special precautions for storage

Protect from light and store in airtight container at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of the container

250 g white powder packed in a 400 ml Black PET container with a Black Biogen embossed and ribbed screwcap lid and a silica gel desiccant.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: info@biogen.co.za


Website: www.biogen.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

JOB: BPS_Biogen Beta Alanine		SIZE: 200mm x 240mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
 K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss	
		<input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY			
<small>Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.</small>			