

Professional Information for PEPTOPRO®

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: PEPTOPRO® oral powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose contains:

Scoops - level		1,5 x 	2,5 x 	3 x 
Each dose contains	Per 100g	Per 12 g	Per 18 g	Per 24 g
Energy	1470 kJ / 350 kcal	176 kJ / 42 kcal	265 kJ / 63 kcal	353 kJ / 84 kcal
Casein protein hydrolysate	85 g	10,2 g	15,3 g	20,4 g
Total Fat	0 g	0 g	0 g	0 g
Carbohydrates	0 g	0 g	0 g	0 g

Amino acid profile:

Scoops - level		1,5 x 	2,5 x 	3 x 
Each dose contains		Per 12 g	Per 18 g	Per 24 g
Glutamine (Glutamic acid)		2,7 g	4,05 g	5,4 g
Proline		1,26 g	1,88 g	2,52 g
Leucine*^		1,18 g	1,77 g	2,36 g
Lysine*		1,02 g	1,53 g	2,04 g
Valine*^		0,82 g	1,22 g	1,64 g
Asparagine (Aspartic acid)		0,81 g	1,21 g	1,62 g
Tyrosine		0,72 g	1,08 g	1,44 g
Serine		0,71 g	1,06 g	1,42 g
Phenylalanine*		0,65 g	0,98 g	1,30 g
Isoleucine*^		0,63 g	0,95 g	1,26 g
Threonine*		0,53 g	0,79 g	1,06 g
Arginine		0,46 g	0,69 g	0,92 g
Methionine*		0,41 g	0,62 g	0,82 g
Histidine*		0,39 g	0,59 g	0,78 g
Alanine		0,36 g	0,55 g	0,72 g
Glycine		0,27 g	0,41 g	0,54 g
Tryptophane*		0,17 g	0,26 g	0,34 g
Cysteine		0,09 g	0,13 g	0,18 g
* Essential amino acids				
^ Branched chain amino acids				

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.



















Dry white powder.


4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PEPTOPRO® is a protein-based workout supplement that contains a wide variety of amino acids for athletic support. Protein helps build and repair body tissues and contributes to the maintenance of muscle mass, and amino acids are involved with muscle protein synthesis.

4.2 Posology and method of administration

WEIGHT	 50 kg	 75 kg	 100 kg	CONSUMPTION
 DURING EXERCISE	500 ml Flavoured Energy Drink	500-750 ml Flavoured Energy Drink	850 ml Flavoured Energy Drink	 Drink 200-250 ml Every 15-30 min
	1.5 x 	2.5 x 	3 x 	
 AFTER EXERCISE	500 ml Flavoured Energy Drink	500-750 ml Flavoured Energy Drink	850 ml Flavoured Energy Drink	
	1.5 x 	2.5 x 	3 x 	
 Enhance recovery by adding ADDITIONALLY	AFTER EXTREME EXERCISE			 Bottle Size 500-850 ml Drink within 30 min after exercise
	1 x 	2 x 	2.5 x 	

PREPARATION	
 1 Mix into your favourite, non-carbonated energy drink.	 2 Close lid tightly. Shake bottle well and wait for the foam to settle before drinking.

Peptides are bitter by nature – adjust the amount of water to taste. Best consumed chilled. Do not exceed the recommended dosage.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Sufficient protein is provided in normal well-balanced daily meals.

Do not exceed daily dosage level without consulting a relevant healthcare provider.

If you have liver or kidney disease, consult a relevant healthcare provider prior to use.

PEPTOPRO® is not suitable for children under the age of 18.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

PEPTOPRO® is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

PEPTOPRO® is generally well tolerated.

Immune system disorders:

Less frequent: hypersensitivity reaction

Gastrointestinal disorders:

Less frequent: diarrhoea, nausea, vomiting, delayed gastric emptying.

Reporting of suspected adverse reactions

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

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.1 Amino acids.

Mechanism of action:

Casein protein is the major protein found in cow's milk and is considered a complete protein. Proteins are constituents of living cells essential for growth and repair of tissues.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic acid.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in dry place with the lid tightly closed once opened.

6.5 Nature and contents of container

400 g powder and a measuring scoop in a round white plastic tub, with an orange plastic screw on lid, containing a patient information leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Unit 6

10 Church Street

Durbanville, Cape Town 7551

Marketed by:

At Life Products South Africa (Pty) Ltd

6 Rautenbach Ave, Wynberg

Sandton

Gauteng

South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

Will be allocated by SAHPRA upon registration.