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: SO

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 a	0 a	0 a	0 a

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.

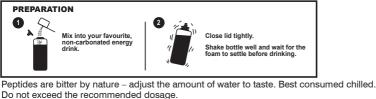
4. CLINICAL PARTICULARS

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	ॐ 50 kg	₹ 75 kg	3 100 kg	CONSUMPTION		
DURING	500 ml Flavoured Energy Drink	500-750 ml Flavoured Energy Drink	850 ml Flavoured Energy Drink	Drink 200-250 ml		
DURING EXERCISE	1.5 x	2.5 x	3 x 🗆	Every 15-30 min		
Y AFTER	500 ml Flavoured Energy Drink	500-750 ml Flavoured Energy Drink	850 ml Flavoured Energy Drink			
AFTER EXERCISE						
AFTER EXERCISE	1.5 x	Energy Drink	Energy Drink	Bottle Size		



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

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

See section 4.8

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Category and class: D 34.1 Amino a

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 Bryanston Ridge Office Park, Block B

13A Bruton Road Corner Main & Bruton Roads Bryanston, 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.