

Professional Information for PEPTOSPORT® CITRUS

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: PEPTOSPORT® oral powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose contains:

Scoops - level	4 x 	6 x 	8 x 	
Each dose contains	Per 100g	Per 55 g	Per 82 g	Per 110 g
Energy	1656 kJ / 396 kcal	911 kJ / 218 kcal	1358 kJ / 324 kcal	1822 kJ / 435 kcal
Casein protein hydrolysate (PeptoPro®)	18,5 g	10,2 g	15,3 g	20,4 g
Total Fat	0 g	0 g	0 g	0 g
Carbohydrates	72,8 g	40 g	60 g	80 g
Total dietary fibre (Inulin)	3,1 g	1,7 g	2,6 g	3,4 g
Sodium chloride	205 mg	113 mg	168 mg	226 mg

Amino acid profile:

Scoops - level	4 x 	6 x 	8 x 
Each dose contains	Per 55 g	Per 82 g	Per 110 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

Excipients with known effect:

Contains sugar:

Each scoop contains 5 g maltodextrin, 2,5 g fructose and 2,5 g sucrose.

Contains sweeteners:

Each scoop contains 4 mg acesulfame potassium and 4 mg sucralose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.

Dry, light yellow powder.



















4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PEPTOSPORT® is a workout supplement that contains proteins, carbohydrates and 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.

Carbohydrates provide fuel that is important for muscle contraction during prolonged exercise performed at moderate intensity, and short duration exercise performed at high intensity.

4.2 Posology and method of administration

WEIGHT	 50 kg	 75 kg	 100 kg	CONSUMPTION
 DURING EXERCISE	500 ml Water	500 - 750 ml Water	850 ml Water	 Drink 200-250 ml Every 15-30 min
	4 x 	6 x 	8 x 	
 AFTER EXERCISE	500 ml Water	500 - 750 ml Water	850 ml Water	
	4 x 	6 x 	8 x 	
 Enhance recovery by adding ADDITIONAL PeptoPro®	PEPTOPRO® AFTER EXTREME EXERCISE			 Bottle Size 500-850 ml Drink within 30 min after exercise
	1 x 	2 x 	2.5 x 	



Do not exceed the recommended dosage.

Best consumed chilled.

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 the daily dosage level without consulting a relevant healthcare provider.

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

PEPTOSPORT® is not suitable for children under the age of 18

PEPTOSPORT® contains sodium

PEPTOSPORT® contains 28,25 mg sodium per scoop, equivalent to 1,4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

PEPTOSPORT® contains sugar: sucrose, fructose and maltodextrin

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take PEPTOSPORT®.

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

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

4.8 Undesirable effects

PEPTOSPORT® 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 PEPTOSPORT® is important. It allows continued monitoring of the benefit/risk balance of PEPTOSPORT®. 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

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.

Carbohydrates provide fuel that is important for muscle contraction during prolonged exercise performed at moderate intensity, and short duration exercise performed at high intensity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium

Beta-carotene (Colourant)

Citric acid

Fructose

Inulin

Maltodextrin

Mandarin flavouring

Orange flavouring

Silicon dioxide

Sodium chloride

Sucralose

Sucrose.

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

900 g powder and a measuring scoop in a round white plastic tub, with a red 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/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

Will be allocated by SAHPRA upon registration.