Professional Information for OSOLEAN®

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
OSOLEAN® ORAL POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 6,1 g (1 scoop) contains:

Mannatein® blend	6,05 g
(hydrolysed whey protein isolate/mineral complex)	
providing protein	(5 g)
calcium	(112,5 mg)

Sugar free.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Oral powder.
Off-white, free-flowing powder with a bland, slightly milky flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
OSOLEAN® is a workout supplement that assists in the building of lean muscle mass while assisting with weight loss when combined with regular weight/resistance training and an energy-reduced diet. OSOLEAN® also increases protein intake to assist with feeling of fullness and to support a healthy, balanced lifestyle. Do not use OSOLEAN® continuously for more than 2 months without consulting a registered health care provider. OSOLEAN® is not intended to treat obesity.

4.2 Posology and method of administration
For adults only.
Mix 2 scoops (12,2 g) in 250 mL of liquid or add to food twice daily. For best results, take with 250 mL of liquid 20 minutes before breakfast and 20 minutes before dinner.
Do not exceed the recommended daily dosage.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or any of the excipients listed in section 2 or 6.1. This includes hypersensitivity to soy from soybean lecithin or milk.

4.4 Special warnings and precautions for use

- OSOLEAN® is not a meal replacement and should not replace normal, well-balanced daily meals which provide sufficient protein.
- The daily dosage level of OSOLEAN® should not be exceeded without consulting a relevant health care provider.
- OSOLEAN® is not suitable for children under the age of 18.

OSOLEAN® contains sodium
OSOLEAN® contains 19,5 mg sodium per scoop, equivalent to 1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicines and other forms of interaction

Antibiotics:
OSOLEAN® may decrease the absorption of antibiotics. Patients should be advised to take antibiotics at least 2 hours prior, or 4 – 6 hours after OSOLEAN®.

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

OSOLEAN® is unlikely to affect the ability to drive a vehicle and use machines.

4.8 Undesirable effects

OSOLEAN® is generally well tolerated.

Skin and subcutaneous tissue disorders:
Frequency unknown: acne.

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

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). Overdose treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.1 Amino acids.

Mechanism of action:

Proteins are constituents of living cells essential for growth and repair of tissues.

Whey protein isolate is a source of amino acids which may assist with muscle protein synthesis.

5.2 Pharmacokinetic properties

Whey protein isolate is metabolised by digestive enzymes and is excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium
Soybean lecithin.

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 a dry place.
Keep in the outer container until required for use.
Do not use if inner seal is missing or broken.
Keep bottle tightly closed.

6.5 Nature and contents of container

White HDPE container with a white cap containing 366 g powder and a clear measuring scoop.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville, 7551
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

This leaflet was last revised in October 2021.

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