Professional Information for OSOLEAN® CHOCOLATE

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® CHOCOLATE ORAL POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 17 g (1 scoop) contains:

Mannatein® blend	12,1 g
(hydrolysed whey protein isolate/mineral complex)	
providing protein	(10 g)
calcium	(200 mg)

Excipient with known effect:
Contains sweetener (14 mg thaumatin per scoop).
Contains sugar (42 mg sucrose per scoop).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Oral powder.
Light brown, free-flowing powder with a chocolate flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
OSOLEAN® CHOCOLATE is a workout supplement that may assist 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® CHOCOLATE also increases protein intake to assist with a feeling of fullness and to support a healthy, balanced lifestyle. Do not use OSOLEAN® CHOCOLATE continuously for more than 2 months without consulting a registered health care provider. OSOLEAN® CHOCOLATE is not intended to treat obesity.

4.2 Posology and method of administration
For adults only.
Mix 1 scoop (17 g) in 250 – 300 mL of liquid or add to food twice daily.
For best results, take with 250 – 300 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® CHOCOLATE is not a meal replacement and should not replace normal, well-balanced daily meals which provide sufficient protein.
- The daily dosage level of OSOLEAN® CHOCOLATE should not be exceeded without consulting a relevant health care provider.
- OSOLEAN® CHOCOLATE is not suitable for children under the age of 18.

OSOLEAN® CHOCOLATE contains sodium
OSOLEAN® CHOCOLATE contains 150 mg sodium per scoop, equivalent to 7,5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

OSOLEAN® CHOCOLATE contains sugar
OSOLEAN® CHOCOLATE contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take OSOLEAN® CHOCOLATE.

4.5 Interaction with other medicines and other forms of interaction

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

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

4.8 Undesirable effects

OSOLEAN® CHOCOLATE is generally well tolerated.

Gastrointestinal disorders:
Frequency unknown: bloating, cramps, nausea, reflux, reduced appetite, thirst.

Skin and subcutaneous tissue disorders:
Frequency unknown: acne.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of OSOLEAN® CHOCOLATE is important. It allows continued monitoring of the benefit/risk balance of OSOLEAN® CHOCOLATE. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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.

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

Cacao powder
Flavourants (chocolate, natural and masking flavour)
Guar gum
Sodium
Soybean lecithin
Thaumatin.

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.
Contents may settle during shipping.

6.5 Nature and contents of container

HDPE container with a cap containing 510 g powder and a 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

January 2026

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