Professional Information for EM•PACT®

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
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
EM•PACT® POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 14 g serving (2 scoops) contains:

Ambrotose® Complex	20 mg
Larix laricina (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	(8 mg)
Aloe vera (L.) Burm.f. (Aloe) [dry inner leaf juice]	(4 mg)
Astragalus gummifer Labill. (Tragacanth) [stem]	(4 mg)
Anogeissus latifolia (Roxb. ex DC.) Wall. ex Guillem. & Perr. (Ghatti gum) [exudate]	(4 mg)
Energy and endurance complex	12,6 g
Fructose	(11,6 g)
Silicon dioxide	(280 mg)
providing elemental silicon	[131 mg]
Medium chain triglycerides	(200 mg)
Magnesium aspartate	(100 mg)
providing elemental magnesium	[20 mg]
Magnesium succinate	(100 mg)
providing elemental magnesium	[17 mg]
Potassium aspartate	(100 mg)
providing elemental potassium	[23 mg]
Potassium succinate	(100 mg)
providing elemental potassium	[33 mg]
L-carnitine	(40 mg)
Choline bitartrate	(40 mg)
providing choline	[20 mg]
Soybean lecithin	(10 mg)

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Excipients with known effect:
Contains sugar (11, 6 g fructose per serving of 2 scoops).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.
Off-white, crystalline powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

EM•PACT® is a combination complementary medicine to assist energy levels during times of strenuous physical activity.

4.2 Posology and method of administration

Adults: Mix two scoops (14 g) of EM•PACT® drink mix with 250 – 500 mL (one serving) or mix the contents of the entire jar into 5 litres of water. For best results, drink one serving 15 – 20 minutes prior to your exercise routine. Additional EM•PACT® drink servings can be consumed during workouts extending beyond one hour.
Do not exceed the recommended dosage.

4.3 Contraindications

- Hypersensitivity to any of the ingredients listed in section 2 or to any of the excipients listed in section 6.1.
- Abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, haemorrhoids or diarrhoea.
- Pregnancy or lactation

4.4 Special warnings and precautions for use

Surgery:
EM•PACT® might interfere with blood glucose control and increase the risk of bleeding during and after surgical procedures. Patients should be advised to discontinue EM•PACT® at least 2 weeks prior to any surgical procedures (see section 4.5).

Liver, kidney and seizure disorders:
Patients with a liver disease, kidney disease, or a seizure disorder should consults a health care provider prior to use.

Gastro-intestinal disorders:
Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting, bloody diarrhoea or fever should consult a health care provider prior to use.

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking EM•PACT®, patients should stop taking EM•PACT® or reduce the dose.

Cross-sensitivity:
Patients allergic to peanuts and soybean (the Fabaceae / Leguminosea family) might have an allergic reaction to EM•PACT®.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:
EM•PACT® may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antibiotic medicines:
Concomitant use of certain antibiotic medicines with EM•PACT® may decrease its effectiveness. The administration of antibiotic medicines and EM•PACT® should be separated by at least 2 hours.

Medicines causing electrolyte imbalances:
Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines), thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult with a health care provider prior to use.

4.6 Fertility, pregnancy and lactation

EM•PACT® should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

EM•PACT® is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:
Less frequent: hypersensitivity/allergic reactions

Gastrointestinal disorders:

Frequent:	diarrhoea, gastrointestinal irritation, nausea, vomiting.
Less frequent:	bloating, flatulence, upset stomach, belching, abdominal discomfort.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of EM•PACT® is important. It allows continued monitoring of the benefit/risk balance of EM•PACT®. 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.
In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product.

Mechanism of action:
Aloe has anti-inflammatory, antioxidant and and immune-boosting properties.
Larch arabinogalactan has immune-boosting properties.
When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool mass and decreases gastrointestinal (GI) transit time.
Magnesium contributes to the maintenance of normal muscle function.
Medium chain triglycerides are made from hydrolyzed coconut oil or palm kernel oils and provides nutritional support during athletic performance.
Choline helps support liver function and is a factor in the maintenance of good health.
Silicon, a trace mineral found in the body, plays a key role in bone regeneration and increasing bone mineral density.
Soybean oil is a rich source of polyunsaturated fatty acids, containing more than 50 % linoleic acid and less than 10 % palmitic acid.
L-carnitine support muscle tissue repair in individuals involved in resistance training, improve physical performance when used in conjunction with a training regimen and delays fatigue during physical activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium citrate
Citric acid (E330)
Lemon oil powder.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

9 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.
Keep the bottle tightly closed.
Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

Silver HDPE container with a silver polypropylene cap.
Pack size: 364 g.

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

September 2021.

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