



# Professional Information for CARDIOBALANCE®

## 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

CARDIOBALANCE® CAPSULES

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Ascorbic acid (Vitamin C)	44,96 mg
D-alpha-tocopheryl providing Vitamin E	2,74 mg 1,05 IU
D-alpha-tocopheryl acetate providing Vitamin E	13 mg 10,18 IU
Cyanocobalamin (Vitamin B <sub>12</sub> )	12,53 µg
Pyridoxal 5-phosphate (Vitamin B <sub>6</sub> )	0,50 mg
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )	2,25 mg
Magnesium citrate providing elemental magnesium	6,40 mg (0,97 mg)
Magnesium glycinate providing elemental magnesium	7,30 mg (1,04 mg)
Magnesium oxide providing elemental magnesium	45,40 mg (25,06 mg)
Folic acid	33,33 µg
L-arginine	253,81 mg
Proprietary herbal blend	67,25 mg
<i>Allium Sativum</i> L. (Garlic) [bulb powder]	(30 mg)
<i>Vitis vinifera</i> L. (Grape) [seed and skin powder]	(22,50 mg)
<i>Crataegus pinnatifida</i> Bunge (Chinese hawthorn) (12,50 mg) [fruit, 10:1 extract, providing 125 mg dried herb equivalent]	
<i>Averrhoa carambola</i> L. (Star fruit) [powder]	(0,75 mg)
<i>Myrciaria dubia</i> (Kunth) McVaugh (Camu Camu) [fruit powder]	(0,75 mg)
<i>Malpighia glabra</i> L. (Acerola) [fruit powder]	(0,75 mg)

Alpha lipoic acid	15 mg
N-acetyl-L-cysteine	12,88 mg
Ambrocosan <sup>®</sup> complex	6,30 mg
Ambrotose <sup>®</sup> Complex	(3,75 mg)
providing <i>Larix laricina</i> (Du Roi) K. Koch or	[1,5 mg]
<i>Larix occidentalis</i> Nutt. (Larch	
Arabinogalactan)	
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	[0,75 mg]
[dry inner leaf juice]	
<i>Astragalus gummifer</i> Labill. (Tragacanth)	[0,75 mg]
[stem]	
<i>Anogeissus latifolia</i> (Roxb. ex DC.)	[0,75 mg]
Wall.ex Guillem. & Perr. (Ghatti gum)	
[exudate]	
Policosanol	(2,5 mg)
[from sugar cane wax]	
Coenzyme Q <sub>10</sub>	1,4 mg

Sugar free.

For the full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Hard capsules.

Pink to tan, clear capsule.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

CARDIOBALANCE<sup>®</sup> is a combination complementary medicine intended to assist in promoting and supporting the function of the heart and the circulatory system.

#### 4.2 Posology and method of administration

*Adults:* Take 2 capsules twice daily, with a glass of water or juice. Use only as directed.

Do not exceed the recommended dosage.

Patients should consult a health care provider for use beyond 3 months.

CARDIOBALANCE<sup>®</sup> can be taken with or without food.

#### Paediatric population:

Not suitable for children.

### 4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 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.
- Patients who had a heart attack/myocardial infarction.
- Pregnancy or lactation (see section 4.6).
- Patients taking antibiotic medicine or nitroglycerin.

### 4.4 Special warnings and precautions for use

#### **Bleeding disorder:**

CARDIOBALANCE® decreases platelet aggregation and may increase the risk of bleeding (see section 4.5).

#### **Hypotension:**

CARDIOBALANCE® might have hypotensive effects and may exacerbate hypotension and lead to syncope in patients with existing low blood pressure (see section 4.5).

#### **Diabetes:**

CARDIOBALANCE® can reduce blood glucose levels and may interfere with blood-glucose control in diabetic patients. Patients with diabetes should consult a relevant health care provider prior to use. If they experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion after taking CARDIOBALANCE®, they should discontinue use and consult a relevant health care provider (see section 4.5).

#### **Surgery:**

CARDIOBALANCE® might cause excessive bleeding, interfere with blood glucose control, or affect blood pressure during or after surgery if used before surgical procedures. Patients should be advised to discontinue CARDIOBALANCE® at least 2 weeks prior to any surgical procedures (see section 4.5).

#### **Cardiovascular conditions:**

Patients should consult a health care provider prior to use if they suffer from cardiovascular disease and are attempting an increase in physical activity or if their cardiovascular condition worsens after taking CARDIOBALANCE®.

**Gastrointestinal conditions:**

Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use.

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking CARDIOBALANCE<sup>®</sup>, patients should stop taking CARDIOBALANCE<sup>®</sup> or reduce the dose.

**Kidney and blood disorders:**

Patients following a low protein diet, with anaemia, a kidney disease or kidney stones, should consult a health care provider prior to use.

**Prolonged use:**

Patients should consult with a relevant health care provider for use beyond 3 months.

**4.5 Interaction with other medicines and other forms of interaction****Anticoagulant or antiplatelet medicines:**

CARDIOBALANCE<sup>®</sup> may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects. Patients should consult with a relevant health care provider prior to use if they are taking blood thinners.

**Antidiabetic medicines**

Concomitant use of CARDIOBALANCE<sup>®</sup> with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

**Antihypertensive medicines:**

CARDIOBALANCE<sup>®</sup> may have hypotensive effects. Concomitant use with antihypertensive medicines may have additive effects on lowering blood pressure and increase the risk of hypotension.

**Cardiac or diuretic medicines:**

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.

**Other medicine:**

Patients taking medicine for erectile dysfunction or protease inhibitors should contact a relevant health care provider prior to use.

#### 4.6 Fertility, pregnancy and lactation

CARDIOBALANCE® should not be used during pregnancy and lactation (see section 4.3).

#### 4.7 Effects on ability to drive and use machines

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

#### 4.8 Undesirable effects

##### **Immune system disorders:**

*Less frequent:* hypersensitivity reactions.

##### **Metabolism and nutrition disorders:**

*Less frequent:* loss of appetite, weight loss.

##### **Nervous system disorders:**

*Frequent:* headache.

*Less frequent:* insomnia.

##### **Gastrointestinal disorders:**

*Frequent:* nausea, vomiting, heartburn, dry mouth, dyspepsia, diarrhoea, abdominal pain, abdominal cramps, flatulence, gastrointestinal irritation, epigastric discomfort.

*Less frequent:* bloating, upset stomach.

##### **Reporting of suspected adverse reactions:**

Reporting suspected adverse reactions after authorisation of CARDIOBALANCE® is important. It allows continued monitoring of the benefit/risk balance of CARDIOBALANCE®. 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, detoxification 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 weight and decreases gastrointestinal (GI) transit time.

Vitamin B<sub>6</sub> and B<sub>12</sub> are water-soluble vitamins that helps to metabolise carbohydrates, fats and proteins. Vitamin B<sub>6</sub> contributes to tissue formation, and Vitamin B<sub>12</sub> contributes to normal red blood cell formation..

Vitamin C is an antioxidant and plays a role in the maintenance of good health. It helps to metabolise fats and proteins and with tissue formation.

Vitamin E is an antioxidant for the maintenance of good health.

Magnesium helps to metabolise carbohydrates, fats and proteins. It also contributes to the development and maintenance of bones and teeth, tissue formation, and the maintenance of normal muscle function.

Folic acid helps the body to metabolise proteins and form red blood cells.

L-Arginine is a non-essential amino acid involved in muscle protein synthesis and may help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.

Alpha-lipoic acid provides antioxidants for the maintenance of good health and helps to promote healthy glucose metabolism.

N-Acetyl-L-cysteine provides a source of amino acids involved in muscle protein synthesis.

Coenzyme Q10 helps to maintain and support cardiovascular health.

The acerola fruit with its rich source of vitamin C, has antioxidant properties.

Garlic help reduce elevated blood lipid levels (hyperlipidemia) and maintain cardiovascular health in adults.

Grape seed extract provides antioxidants and helps to relieve symptoms related to non-complicated chronic venous insufficiency (CVI), such as sensation of swelling, heaviness and tingling of the legs.

Camu camu contains antioxidants, including vitamin C.

Star fruit and hawthorn have antioxidant properties.

Hawthorn has traditionally been used for cardiovascular conditions. It acts on the muscular tissue of the heart by increasing the force of contraction and lengthening the refractory period, increasing coronary blood flow and cardiac output, and reducing oxygen consumption.

Policosanol has cholesterol-lowering properties.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Betaine (trimethyl glycine)

Capsule (containing carrageenan, hypromellose and potassium acetate)

Magnesium stearate (E572).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

24 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 the inner seal is missing or broken.

### 6.5 Nature and contents of container

HDPE container with a polypropylene cap containing 120 capsules.

### 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

November 2021.