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PATIENT INFORMATION LEAFLET
CARDIOBALANCE®

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PASIËNTINLIGTINGSBLAD
CARDIOBALANCE®

03

PROFESSIONAL INFORMATION FOR
CARDIOBALANCE®



PATIENT INFORMATION LEAFLET

CARDIOBALANCE®

SCHEDULING STATUS

S0

CARDIOBALANCE® capsules
Multiple substance formulation.
Sugar free.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.

CARDIOBALANCE® is available without a doctor's prescription. Nevertheless, you still need to take CARDIOBALANCE® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CARDIOBALANCE® with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What CARDIOBALANCE® is and what it is used for.
2. What you need to know before you take CARDIOBALANCE®.
3. How to take CARDIOBALANCE®.
4. Possible side effects.
5. How to store CARDIOBALANCE®.
6. Contents of the pack and other information.

1. What CARDIOBALANCE® is and what it is used for

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

2. What you need to know before you take CARDIOBALANCE®

Do not take CARDIOBALANCE®:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of CARDIOBALANCE® (see section 6).
- If you have abnormal constrictions of your digestive tract, or a lazy or blocked large colon (causing chronic constipation).
- If you have appendicitis (inflammation of your appendix).
- If you have an inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis).
- If you have abdominal pain with an unknown cause.
- If you have undiagnosed rectal bleeding.
- If you are severely dehydrated.
- If you have haemorrhoids (piles) or diarrhoea.
- If you have had a heart attack.
- If you are pregnant or breastfeeding.
- If you are taking antibiotic medicines (used to treat bacterial infections) or heart medication called nitroglycerine.

Warnings and precautions

Take special care with CARDIOBALANCE®:

- If you have a bleeding disorder.
- If you have low blood pressure.
- If you are having any surgical procedure done. You should stop taking CARDIOBALANCE® two weeks before an operation.
- If you experience abdominal pain, cramps, spasms and/or diarrhoea after taking CARDIOBALANCE®, you should stop taking CARDIOBALANCE® or reduce your dose of CARDIOBALANCE®.

You should consult with your doctor or health care provider before taking CARDIOBALANCE®:

- If you are diabetic and you are taking medicines to control your blood sugar levels. Stop use and consult your health care provider if you experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion after taking CARDIOBALANCE®.
- If you suffer from a cardiovascular disease and want to increase your physical activity, or if your cardiovascular condition worsens after taking CARDIOBALANCE®.
- If you have a stomach ulcer or excess stomach acid.
- If you have symptoms such as abdominal pain, nausea, vomiting or fever.

- If you are following a low protein diet.
- If you have anaemia (a deficiency of the red blood cells in your body causing fatigue, loss of energy and pale skin).
- If you have kidney problems, including kidney stones.
- You should consult with your health care provider for use beyond 3 months.

Children:

CARDIOBALANCE® is not suitable for children.

Other medicines and CARDIOBALANCE®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects;
- antidiabetic medicine (used to treat high blood sugar);
- antihypertensive medicine (used to lower your blood pressure);
- heart/cardiac medicines (e.g. cardiac glycosides [used to treat heart failure] or antidysrhythmic medicines [used to prevent and treat abnormal heartbeats]);
- diuretics (water pills), corticosteroids (used to treat inflamed areas of your body), liquorice root or other medicines or products that may worsen electrolyte imbalance;
- medicines for erectile dysfunction;
- medicines called protease inhibitors (used to treat human immunodeficiency virus (HIV).

CARDIOBALANCE® with food and drink

See section 3.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CARDIOBALANCE®.

Do not use CARDIOBALANCE® if you are pregnant or breastfeeding (see **Do not take CARDIOBALANCE®**).

Driving and using machines

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

3. How to take CARDIOBALANCE®

Always take CARDIOBALANCE® exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Take 2 capsules twice daily, with a glass of water or juice.

Use only as directed. Do not exceed the recommended dose.

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

CARDIOBALANCE® should be taken with food.

If you have the impression that the effect of CARDIOBALANCE® is too strong or too weak, tell your doctor or pharmacist.

If you take more CARDIOBALANCE® than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the remaining capsules with you so the doctor will know what you have taken.

If you forget to take CARDIOBALANCE®:

Take your next dose at your regular time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CARDIOBALANCE® can have side effects.

Not all side effects reported for CARDIOBALANCE® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARDIOBALANCE®, please consult your health care provider for advice.

If any of the following happens, stop taking CARDIOBALANCE® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CARDIOBALANCE®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- headache;
- nausea (feeling sick), vomiting (being sick), heartburn, dry mouth, indigestion, diarrhoea, stomach pain or cramps, flatulence (wind), upset stomach.

Side effects occurring less frequently:

- loss of appetite, decrease in body mass;
- difficulty falling or staying asleep (insomnia);
- bloating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CARDIOBALANCE®.

5. How to store CARDIOBALANCE®

- 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.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARDIOBALANCE® contains

Each vegetable capsule contains:

Proprietary herbal blend	66,63 mg
<i>Allium sativum</i> L. (Garlic)	(30 mg)
[bulb powder]	
<i>Vitis vinifera</i> L. (Grape)	(23 mg)
[seed and skin extract powder]	
<i>Crataegus pinnatifida</i> Bunge (Chinese hawthorn)	(11,88 mg)
[fruit, 10:1 extract, providing 125 mg dried herb equivalent]	
<i>Malpighia glabra</i> L. (Acerola)	(1 mg)
[fruit powder]	
<i>Myrciaria dubia</i> (Kunth) McVaugh (Camu camu)	(1 mg)
[fruit powder]	
Ambrocosanol® complex	6,3 mg
Ambrotose® Complex	(3,8 mg)
providing <i>Larix laricina</i> (Du Roi) K. Koch	[2,25 mg]
(Larch Arabinogalactan)	
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	[0,8 mg]
[dry inner leaf juice]	
<i>Acacia senegal</i> (L.) Britton (Acacia gum)	[0,75 mg]
[exudate]	
Policosanol	(2,5 mg)
[from sugar cane wax]	
L-arginine	250 mg
Trimethylglycine	62,5 mg

Ascorbic acid (Vitamin C)	45 mg
Alpha lipoic acid	15 mg
N-acetyl-L-cysteine	12,5 mg
Pyridoxine hydrochloride (Vitamin B ₆)	1,4 mg
Pyridoxal 5-phosphate (Vitamin B ₆)	0,42 mg
Coenzyme Q ₁₀	1,3 mg
Magnesium citrate	43 mg
providing elemental magnesium	(6 mg)
Magnesium glycinate	37 mg
providing elemental magnesium	(7 mg)
Magnesium oxide	21,55 mg
providing elemental magnesium	(12,5 mg)
D-alpha-tocopheryl acetate	8,75 mg
providing Vitamin E	5,87 IU
D-alpha-tocopherol	2,5 mg
providing Vitamin E	1,68 IU
Folic acid	106 µg
Cyanocobalamin (Vitamin B ₁₂)	13 µg

The other ingredients are the capsule (containing carrageenan, hypromellose and potassium acetate) and magnesium stearate (E572).

What CARDIOBALANCE® looks like and contents of the pack

Pink to tan, clear capsule.

HDPE container with a polypropylene cap containing 120 capsules.

Holder of Certificate of Registration

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville 7551
South Africa
Tel.: 087 551 3245

This leaflet was last revised in
August 2026

Registration number

To be allocated.

Access to corresponding Professional Information

<https://library.mannatech.com/download/12233>



PASIËNTINLIGTINGSBLAD CARDIOBALANCE® kapsules

SKEDULERINGSSTATUS

S0

CARDIOBALANCE® kapsules
Formule met verskeie bestanddele.
Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.

CARDIOBALANCE® is beskikbaar sonder 'n dokter se voorskrif. Jy moet CARDIOBALANCE® nietemin steeds versigtig gebruik om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie CARDIOBALANCE® met enigiemand anders deel nie.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is CARDIOBALANCE® en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy CARDIOBALANCE® neem.
3. Hoe om CARDIOBALANCE® te neem.
4. Moontlike nuwe-effekte.
5. Hoe om CARDIOBALANCE® te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is CARDIOBALANCE® en waarvoor word dit gebruik

CARDIOBALANCE® is 'n kombinasie- komplementêre medisyne wat bedoel is om te help om die funksie van die hart en bloedsomloopstelsel te bevorder en te ondersteun.

2. Wat jy moet weet voordat jy CARDIOBALANCE® neem

Moenie CARDIOBALANCE® neem nie:

- Indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of enige van die ander bestanddele van CARDIOBALANCE® (sien afdeling 6).
- Indien jy abnormale vernouings van jou spysverteringskanaal, of 'n lui of verstopte dikderm het (wat chroniese hardlywigheid veroorsaak).
- Indien jy appendisitis (blindedermontsteking) het.
- Indien jy 'n inflammatoriese siekte van die kolon het (bv. Crohn se siekte of ulseratiewe kolitis).
- Indien jy buikpyn het waarvan die oorsaak onbekend is.
- Indien jy ongediagnoseerde rektale bloeding het.
- Indien jy erg gedehidreer is.
- Indien jy hemorroïede (aambeie) of diarree het.
- Indien jy al 'n hartaanval gehad het.
- Indien jy swanger is of borsvoed.
- Indien jy antibiotiese medisyne (gebruik om bakteriële infeksies te behandel) of hartmedikasie genaamd nitrogliserien neem.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met CARDIOBALANCE®:

- Indien jy aan 'n bloedingsversteuring ly.
- Indien jy lae bloeddruk het.
- Indien jy enige operasie moet ondergaan. Jy moet twee weke voor chirurgie ophou om CARDIOBALANCE® te neem.
- Indien jy buikpyn, -krampe, -spasmas en/of diarree ondervind nadat jy CARDIOBALANCE® geneem het, moet jy ophou om CARDIOBALANCE® te neem of die dosis daarvan verlaag.

Jy behoort 'n gesondheidsorgverskaffer te raadpleeg voordat jy CARDIOBALANCE® neem:

- Indien jy aan diabetes ly en medisyne neem om jou bloedsuikervlakke te beheer. Hou op om dit te gebruik en raadpleeg jou gesondheidsorgverskaffer indien jy simptome van lae bloedsuiker ondervind nadat jy CARDIOBALANCE® geneem het, soos sweting, bleekheid, koue rillings, hoofpyn, duiseligheid en/of verwarring.
- Indien jy aan 'n kardiovaskulêre siekte ly en jou fisieke aktiwiteit wil verhoog, of indien jou kardiovaskulêre toestand agteruitgaan nadat jy CARDIOBALANCE® geneem het.
- Indien jy 'n maagseer het of oormatige maagsuur het.
- Indien jy simptome soos buikpyn, naarheid, braking of koors het.
- Indien jy 'n lae proteïendieet volg.

- Indien jy anemies is ('n tekort aan rooibloedselle in jou liggaam, wat moegheid, gebrek aan energie en bleekheid veroorsaak).
 - Indien jy nierprobleme het, insluitende nierstene.
- Jy behoort jou gesondheidsorgverskaffer te raadpleeg indien jy dit vir langer as 3 maande wil gebruik.

Kinders:

CARDIOBALANCE® is nie geskik vir kinders nie.

Ander medisyne en CARDIOBALANCE®

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- antikoagulant (gebruik om te voorkom dat jou bloed klonte vorm) of kruie-aanvullings met bloedverdunnende effekte;
- antidiabetiese medisyne (gebruik om hoë bloedsuiker te behandel);
- antihipertensiewe medisyne (gebruik om jou bloeddruk te verlaag);
- hartmedisyne (bv. kardiaale glikosiede [gebruik om hartversaking te behandel] of antidisritmiese medisyne [gebruik om abnormale hartritme te voorkom en te behandel]);
- diuretika (waterpille), kortikosteroïede (gebruik om inflammasie te behandel), soethoutwortel of ander medisyne of produkte wat 'n wanbalans van elektroliete in jou liggaam kan vererger;
- medisyne vir erektiele disfunksie;
- medisyne genaamd protease-inhibeerders (gebruik om infeksie met menslike immuniteitsgebrekvirus [MIV] te behandel).

CARDIOBALANCE® met kos en drinkgoed

Sien afdeling 3.

Swangerskap en borsvoeding

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy CARDIOBALANCE® neem.

Moenie CARDIOBALANCE® neem indien jy swanger is of jou baba borsvoed nie (sien **Moenie CARDIOBALANCE® neem nie**).

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat CARDIOBALANCE® jou vermoë om te bestuur en masjiene te gebruik sal affekteer.

3. Hoe om CARDIOBALANCE® te neem

Neem CARDIOBALANCE® altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes: Neem 2 kapsules met 'n glas water of sap, twee keer per dag. Gebruik slegs soos aangedui. Moenie die aanbevole dosis oorskry nie. Jy moet 'n gesondheidsorgverskaffer konsulteer indien jy dit vir langer as 3 maande wil gebruik. CARDIOBALANCE® moet met kos geneem word.

Indien jy die indruk kry dat die uitwerking van CARDIOBALANCE® te sterk of te swak is, bespreek dit met jou dokter of apteker.

Wat om te doen indien jy meer CARDIOBALANCE® geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die oorblywende kapsules saam sodat die dokter kan sien wat jy of jou kind geneem het.

Indien jy vergeet om CARDIOBALANCE® te neem:

Neem jou volgende dosis op die gewone tyd.

Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

4. Moontlike neue-effekte

CARDIOBALANCE® kan neue-effekte hê.

Nie alle neue-effekte wat vir CARDIOBALANCE® gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy CARDIOBALANCE® neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om CARDIOBALANCE® te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige neue-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige reaksie op CARDIOBALANCE® gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Nuwe-effekte wat dikwels voorkom

- hoofpyn;

- naarheid, braking, sooibrand, droë mond, indigestie, diarree, maagpyn of -krampe, flatulensie (winderigheid), omgekrapte maag.

Neuwe-effekte wat minder dikwels voorkom

- verlies aan eetlus, afname in liggaamsmassa;
- sukkel om aan die slaap te raak of aan die slaap te bly (insomnia);
- opgeblasenheid.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eRapportering-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is.

Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van CARDIOBALANCE® te verskaf.

5. Hoe om CARDIOBALANCE® te bêre

- Bêre by of onder 25 °C, op 'n droë plek.
- Hou die bottel dig toe.
- Moenie gebruik indien die seël aan die binnekant weg of beskadig is nie.
- BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die verpakking gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting

Wat CARDIOBALANCE® bevat

Elke plantaardige kapsule bevat:

Eie kruiemengsel	66,63 mg
<i>Allium sativum</i> L. (Knoffel)	(30 mg)
[bol, poeier]	
<i>Vitis vinifera</i> L. (Druive)	(23 mg)
[saad en dop, ekstrak poeier]	
<i>Crataegus pinnatifida</i> Bunge (Chiniese haagddoring)	(11,88 mg)
[vrug, 10:1 ekstrak, lewer 125 mg droë kruie ekwivalent]	
<i>Malpighia glabra</i> L. (Acerola)	(1 mg)
[vrug, poeier]	
<i>Myrciaria dubia</i> (Kunth) McVaugh (Camu-camu)	(1 mg)

[vrug, poeier]	
Ambrocosanol®-kompleks	6,3 mg
Ambrotose®-kompleks	(3,8 mg)
verskaf <i>Larix laricina</i> (Du Roi) K. Koch	[2,25 mg]
(Lariks arabinogalaktaan)	
<i>Aloe vera</i> (L.) Burm.f. (Aalwyn)	[0,8 mg]
[droë binneste blaarsap]	
<i>Acacia senegal</i> (L.) Britton (Acacia gom)	[0,75 mg]
[eksudaat]	
Polikosanol	(2,5 mg)
[van suikerrietwas]	
L-arginien	250 mg
Trimetielglisien	62,5 mg
Askorbiensuur (Vitamien C)	45 mg
Alfa-lipoïensuur	15 mg
N-asetiel-L-sisteien	12,5 mg
Piridoksienhidrochloried (Vitamien B ₆)	1,4 mg
Piridoksaal-5-fosfaat (Vitamien B ₆)	0,42 mg
Koënsiem Q ₁₀	1,3 mg
Magnesiumsitraat	43 mg
verskaf elementêre magnesium	(6 mg)
Magnesiumglisinaat	37 mg
verskaf elementêre magnesium	(7 mg)
Magnesiumoksied	21,55 mg
verskaf elementêre magnesium	(12,5 mg)
D-alpha-tokoferielasetaat	8,75 mg
verskaf Vitamien E	5,87 IE
D-alpha-tokoferiel	2,5 mg
verskaf Vitamien E	1,68 IE
Foliensuur	106 µg
Sianokobalamien (Vitamien B ₁₂)	13 µg

Die ander bestanddele is die kapsule (wat karrageen, hipromellose en kaliumasetaat bevat) en magnesiumstearaat (E572).

Hoe CARDIOBALANCE® lyk en inhoud van die verpakking

Pienk- tot taankleurige, deurskynende kapsule.

HDPE-houer met 'n polipropileenprop, wat 120 kapsules bevat.

Houer van die Registrasiesertifikaat

LeBasi Pharmaceuticals (Edms.) Bpk.

San Domenico-gebou, Grondvloer, Eenheid 6

Kerkstraat 10

[vrug, poeier]	
Ambrocosanol®-kompleks	6,3 mg
Ambrotose®-kompleks	(3,8 mg)
verskaf <i>Larix laricina</i> (Du Roi) K. Koch	[2,25 mg]
(Lariks arabinogalaktaan)	
<i>Aloe vera</i> (L.) Burm.f. (Aalwyn)	[0,8 mg]
[droë binneste blaarsap]	
<i>Acacia senegal</i> (L.) Britton (Acacia gom)	[0,75 mg]
[eksudaat]	
Polikosanol	(2,5 mg)
[van suikerrietwas]	
L-arginien	250 mg
Trimetielglisien	62,5 mg
Askorbiensuur (Vitamien C)	45 mg
Alfa-lipoïensuur	15 mg
N-asetiel-L-sisteien	12,5 mg
Piridoksienhidrochloried (Vitamien B ₆)	1,4 mg
Piridoksaal-5-fosfaat (Vitamien B ₆)	0,42 mg
Koënsiem Q ₁₀	1,3 mg
Magnesiumsitraat	43 mg
verskaf elementêre magnesium	(6 mg)
Magnesiumglisinaat	37 mg
verskaf elementêre magnesium	(7 mg)
Magnesiumoksied	21,55 mg
verskaf elementêre magnesium	(12,5 mg)
D-alpha-tokoferielasetaat	8,75 mg
verskaf Vitamien E	5,87 IE
D-alpha-tokoferiel	2,5 mg
verskaf Vitamien E	1,68 IE
Foliensuur	106 µg
Sianokobalamien (Vitamien B ₁₂)	13 µg

Die ander bestanddele is die kapsule (wat karrageen, hipromellose en kaliumasetaat bevat) en magnesiumstearaat (E572).

Hoe CARDIOBALANCE® lyk en inhoud van die verpakking

Pienk- tot taankleurige, deurskynende kapsule.

HDPE-houer met 'n polipropileenprop, wat 120 kapsules bevat.

Houer van die Registrasiesertifikaat

LeBasi Pharmaceuticals (Edms.) Bpk.

San Domenico-gebou, Grondvloer, Eenheid 6

Kerkstraat 10



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

S0

1. NAME OF THE MEDICINE

CARDIOBALANCE® CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Proprietary herbal blend	66,63 mg
<i>Allium sativum</i> L. (Garlic)	(30 mg)
[bulb powder]	
<i>Vitis vinifera</i> L. (Grape)	(23 mg)
[seed and skin extract powder]	
<i>Crataegus pinnatifida</i> Bunge (Chinese hawthorn)	(11,88 mg)
[fruit, 10:1 extract, providing 125 mg dried herb equivalent]	
<i>Malpighia glabra</i> L. (Acerola)	(1 mg)
[fruit powder]	
<i>Myrciaria dubia</i> (Kunth) McVaugh (Camu camu)	(1 mg)
[fruit powder]	
Ambrocosanol® complex	6,3 mg
Ambrotose® Complex	(3,8 mg)
providing <i>Larix laricina</i> (Du Roi) K. Koch	[2,25 mg]
(Larch Arabinogalactan)	
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	[0,8 mg]
[dry inner leaf juice]	
<i>Acacia senegal</i> (L.) Britton (Acacia gum)	[0,75 mg]
[exudate]	
Policosanol	(2,5 mg)
[from sugar cane wax]	
L-arginine	250 mg
Trimethylglycine	62,5 mg
Ascorbic acid (Vitamin C)	45 mg
Alpha lipoic acid	15 mg
N-acetyl-L-cysteine	12,5 mg
Pyridoxine hydrochloride (Vitamin B ₆)	1,4 mg
Pyridoxal 5-phosphate (Vitamin B ₆)	0,42 mg

Coenzyme Q ₁₀	1,3 mg
Magnesium citrate	43 mg
providing elemental magnesium	(6 mg)
Magnesium glycinate	37 mg
providing elemental magnesium	(7 mg)
Magnesium oxide	21,55 mg
providing elemental magnesium	(12,5 mg)
D-alpha-tocopheryl acetate	8,75 mg
providing Vitamin E	5,87 IU
D-alpha-tocopherol	2,5 mg
providing Vitamin E	1,68 IU
Folic acid	106 µg
Cyanocobalamin (Vitamin B ₁₂)	13 µg

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® 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® should be taken with 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 a peptic ulcer or excess stomach acid should consult a health care provider before use.

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®, patients should stop taking CARDIOBALANCE® 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® 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® 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® 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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.

Trimethylglycine aids in digestion.

Vitamin B₆ and B₁₂ are water-soluble vitamins that helps to metabolise carbohydrates, fats and proteins. Vitamin B₆ contributes to tissue formation, and Vitamin B₁₂ 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

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

August 2026