

**COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT**

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

SCHEDULING STATUSS₀**1. NAME OF THE MEDICINE**

CATALYST HEART AND CARDIOVASCULAR HEALTH WITH COENZYME Q₁₀ AND VITAMK7[®] capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Magnesium glycinate	200 mg
providing magnesium (elemental)	25 mg
Ubiquinol (coenzyme Q ₁₀)	30 mg
VITAMK7 [®]	30 mg
providing vitamin K ₂	60 µg
Cholecalciferol (vitamin D ₃)	10 mg (1000 IU)

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule.

White capsules containing yellow coloured powder.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

CATALYST HEART AND CARDIOVASCULAR HEALTH is a vitamin/mineral supplement with antioxidant properties that assists with the maintenance of good health. It can assist in the development and maintenance of bones and teeth, with the absorption and use of calcium, and it helps support muscle function and cardiovascular health.

4.2 Posology and method of administration

Adults: Take 1 capsule daily.

Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to vitamin K₂, coenzyme Q₁₀, vitamin D₃, magnesium or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use**Hypotension:**

CATALYST HEART AND CARDIOVASCULAR HEALTH might have hypotensive effects and may exacerbate hypotension in patients with existing low blood pressure. CATALYST HEART AND CARDIOVASCULAR

HEALTH might interfere with blood pressure control during and after surgery. Patients should therefore be advised to discontinue CATALYST HEART AND CARDIOVASCULAR HEALTH at least 2 weeks prior to any surgical procedures.

Hypercalcaemia:

CATALYST HEART AND CARDIOVASCULAR HEALTH may increase calcium levels. Caution is advised in patients with an increased risk of developing hypercalcaemia.

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

CATALYST HEART AND CARDIOVASCULAR HEALTH might reduce the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects.

Antihypertensive medicines:

Concomitant use with antihypertensive medicines may have additive effects on lowering blood pressure and increase the risk of hypotension (see section 4.4).

Antibiotics:

CATALYST HEART AND CARDIOVASCULAR HEALTH may decrease the absorption of quinolone and tetracycline antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking CATALYST HEART AND CARDIOVASCULAR HEALTH.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

CATALYST HEART AND CARDIOVASCULAR HEALTH should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

CATALYST HEART AND CARDIOVASCULAR HEALTH is unlikely to affect the ability to drive a vehicle and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of CATALYST HEART AND CARDIOVASCULAR HEALTH are known.

4.8 Undesirable effects

CATALYST HEART AND CARDIOVASCULAR HEALTH is generally well tolerated.

Gastrointestinal disorders:

<i>Frequent:</i>	nausea, diarrhoea, abdominal upset
<i>Frequency unknown:</i>	vomiting, appetite suppression, heartburn, epigastric discomfort

Skin and subcutaneous tissue disorders:

Less frequent: skin and skin appendage lesions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of CATALYST HEART AND CARDIOVASCULAR HEALTH is important. It allows continued monitoring of the benefit/risk balance of CATALYST HEART AND CARDIOVASCULAR HEALTH. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug

Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

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 34.12 Multiple substance formulation.

Mechanism of action:

Vitamin K is a fat-soluble vitamin that contributes to the maintenance of normal bones.

Coenzyme Q₁₀ is a vitamin-like compound present in virtually all cells. It has antioxidant properties and plays an important role in the production of ATP, necessary for cellular energy production.

Coenzyme Q₁₀ also helps support cardiovascular health. It increases plasma levels of high-density lipoprotein (HDL) cholesterol, vitamin E and vitamin C; and decreases levels of total cholesterol and low-density lipoprotein (LDL) cholesterol.

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

Vitamin D₃ is a fat-soluble vitamin that contributes to the development and maintenance of bones and teeth, and helps with the absorption and use of calcium.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Microcrystalline cellulose (E460(i))

Silicon dioxide (E551)

Vegetable capsule (containing hypromellose (E551) and titanium dioxide (E171)).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

6.5 Nature and contents of container

175 mL amber PET jars with white flip top lids with a white shrink sleeve.

Pack size: 30 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, Unit 6

10 Church Street

Durbanville 7550

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

October 2020.