Professional Information for CATALYST™

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
CATALYST™ TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

Vitamins	
Ascorbic acid (vitamin C)	90 mg
D-calcium pantothenate	13 mg
providing pantothenic acid (vitamin B_5)	10 mg
Niacinamide (vitamin B_3)	5 mg
Pyridoxine hydrochloride	2,25 mg
providing pyridoxine (vitamin B_6)	1,5 mg
Pyridoxal-5-phosphate monohydrate	0,4 mg
providing pyridoxine (vitamin B_6)	0,33 mg
Riboflavin (vitamin B_2 from Ashbya gossypii yeast)	1,7 mg
Thiamine mononitrate	2 mg
providing thiamine (vitamin B_1)	1,5 mg
Beta-carotene (vitamin A)	253 IU
Cholecalciferol (vitamin D_3)	100 IU
Vitamin E (as d-alpha-tocopheryl succinate, mixed tocopherols and tocotrienols)	15 IU
Folic acid	100 µg
Biotin	75 µg
Cyanocobalamin (vitamin B_{12})	6 µg
Minerals	
Calcium carbonate	700 mg
providing calcium (elemental)	249 mg
Calcium citrate malate glycinate	5 mg
providing calcium (elemental)	1 mg
glycine	0,8 mg

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Magnesium oxide	100 mg
providing magnesium (elemental)	52 mg
Magnesium glycinate	35,5 mg
providing magnesium(elemental)	5 mg
glycine	15,5 mg
Zinc glycinate	19 mg
providing zinc (elemental)	3,75 mg
glycine	6,9 mg
Boron glycinate	10 mg
providing boron (elemental)	0,5 mg
glycine	3,4 mg
Copper bislgycinate	5 mg
providing copper (elemental)	0,5 mg
glycine	1,8 mg
Manganese glycinate	3,2 mg
providing manganese (elemental)	0,45 mg
glycine	1,2 mg
Chromium nicotinate glycinate	2 100 µg
providing chromium (elemental)	50 µg
glycine	0,4 mg
Selenium L-methionine	10 000 µg
providing selenium (elemental)	50 µg
L-methionine	8 mg
Vanadium glycinate	2 200 µg
providing vanadium (elemental)	40 µg
glycine	1,7 mg
Potassium iodide	50 µg
providing iodine (elemental)	37,5 µg
Molybdenum glycinate	9 400 µg
providing molybdenum (elemental)	18,75 µg
glycine	0,2 mg
Amino Acids	
Total glycine (as magnesium glycinate, zinc glycinate, boron glycinate, calcium citrate malate glycinate, manganese glycinate, vanadium glycinate, chromium nicotinate glycinate, copper bisglycinate & molybdenum glycinate)	31,9 mg
L-methionine (as selenium L-methionine)	8 mg
Arthrospira plantensis Gomont (Spirulina) powder	50 mg
Ambroglycin®	46 mg
providing *Nasturtium officinale* R.Br (Watercress) [leaf powder]	16 mg
Pisum sativium L. (Green pea) fiber [dried field pea hulls]	9,7 mg

Spinacia oleracea L. (Spinach) [leaf powder]	9,7 mg
Zingiber officinale Roscoe (Ginger) [root powder]	9,7 mg
Ambrotose® Complex	1 mg
providing *Larix laricina* (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	0,4 mg
Aloe vera (L.) Burm.f. (Aloe) [inner leaf juice powder]	0,2 mg
Anogeissus latifolia (Roxb. Ex DX.) Wall. Ex Guilem. & Perr. (Ghatti gum) [exudate]	0,2 mg
Astragalus gummifer Labill. (Tragacanth)	0,2 mg
Lecithin (from *Helianthus annuus* L. seed)	12,5 mg
Phytonutrient complex 2	12,5 mg
providing *Citrus x aurantium* L. (Orange) [peel powder]	2,5 mg
Glycine max L. (Soy Protein Isolate)	2,5 mg
Malpighia glabra L. (Acerola) [fruit, 4:1 extract providing 10 mg of dried herb equivalent]	2,5 mg
Oryza sativa L. (Rice bran) powder	2,5 mg
Rosa canina L. (Rose hip) powder	2,5 mg
Inositol	6,25 mg
Alpha Lipoic Acid	3,75 mg
Coenzyme Q10 (Ubidecarenone)	3 mg

Sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
Green, modified, oblong, clear film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CATALYST™ is a combination complementary medicine intended to supplement the diet with vitamins, minerals, trace minerals, antioxidants and herbal extracts to assist and support general well-being.

4.2 Posology and method of administration

Adults:
Take two tablets twice daily (in the morning and afternoon) with 250 mL of water or juice.

Do not exceed the recommended dosage.

Children:
Not suitable for children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1. This includes hypersensitivity to egg or soy.
- 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, intestinal ulcerations or diarrhoea.
- Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Surgery:
CATALYST™ may increase the risk of bleeding or interfere with blood glucose control if used perioperatively. Patients should be advised to discontinue CATALYST™ at least 2 weeks prior to any surgical procedures.

Gastrointestinal conditions:
Patients with gastric or duodenal ulcers should not take CATALYST™ due to its potential to irritate the gastrointestinal mucosa.
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 CATALYST™, patients should stop taking CATALYST™ or reduce the dose.

Kidney disorders:
Patients with inflammatory kidney disease should not take CATALYST™. CATALYST™ may exacerbate kidney disfunction in patients with existing kidney disease. Patients should consult a health care provider prior to use.

Diabetes mellitus:
CATALYST™ may affect blood glucose levels and dose adjustment of antidiabetic medicine might be necessary (see section 4.5). Patients should consult a health care provider prior to use.
Patients should discontinue use and consult a relevant health care provider if they experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion.

Patients should consult a relevant health care provider before use if they have acidosis, atherosclerosis, or methylenetetrahydrofolate reductase deficiency.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

CATALYST™ may potentiate the effects of anticoagulant or antiplatelet medicines or herbal supplements with blood thinning effects. Concomitant use may increase the risk of bruising and bleeding.

Antidiabetic medicines:

Concomitant use of CATALYST™ with antidiabetic medicines or herbal supplements with hypoglycaemic potential may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antibiotic medicines:

CATALYST™ may reduce the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking CATALYST™.

Cardiac medicines:

Patients taking cardiac medicines (e.g. cardiac glycosides, antidysrhythmic medicines or antihypertensive medicines) should consult a health care provider prior to use.

Medicines causing electrolyte imbalances:

Patients taking thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult a health care provider prior to use.

Levothyroxine:

CATALYST™ may reduce levothyroxine absorption. Advise patients to take levothyroxine and CATALYST™ at least 4 hours apart.

Clozapine:

Concomitant use of CATALYST™ with clozapine may worsen symptoms in patients with schizophrenia. Use with caution.

Lithium:

CATALYST™ may affect serum lithium levels. Use with caution.

4.6 Fertility, pregnancy and lactation

CATALYST™ contains aloe vera which is contraindicated during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

CATALYST™ may cause side effects, such as dizziness, and can affect the ability to drive and use machines. Caution is advised when driving

a vehicle or operating machinery until the effects of CATALYST™ are known.

4.8 Undesirable effects

CATALYST™ is generally well tolerated.

Immune system disorders:
Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:
Frequency unknown: loss of appetite.

Psychiatric disorders:
Frequency unknown: insomnia.

Nervous system disorders:
Frequency unknown: dizziness, fatigue, drowsiness, headache.

Vascular disorders:
Frequency unknown: flushing.

Gastrointestinal disorders:
Frequency unknown: abdominal pain and cramps, stomach upset, bloating, flatulence, belching, indigestion, nausea, vomiting, diarrhoea, constipation.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of CATALYST™ is important. It allows continued monitoring of the benefit/risk balance of CATALYST™. 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.

Calcium contributes to the development and maintenance of bones and teeth and is a factor in the maintenance of good health. Calcium absorption is affected by several factors like age, race, environmental and

dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Magnesium, a mineral that contributes to the maintenance of good health, has antioxidant and immune-boosting properties. It is absorbed throughout the gastrointestinal tract, distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Ascorbic acid (vitamin C) is a water-soluble vitamin with antioxidant properties. It helps to maintain proper immune function and to metabolise fats and proteins. It is readily absorbed from the gastrointestinal tract and is primarily excreted in the urine.

Arthrospira plantensis Gomont (Spirulina) is a blue-green algae that is a rich source of nutrients including protein and has antioxidant and immune-boosting properties.

Choline has antioxidant properties and may assist with cognitive function. It has very slow oral absorption. Unabsorbed choline is metabolised by intestinal bacteria to trimethylamine and oral choline has an elimination half-life of up to 56 hours.

Zinc helps to maintain immune function and helps the body to metabolise carbohydrates, fats and proteins. It is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.

Pantothenic acid (vitamin B_5) is an essential B vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is the precursor of coenzyme A (CoA) and is excreted in the urine.

Boron is a trace mineral that is a factor in the maintenance of good health. It is well-absorbed from the gastrointestinal tract and is excreted unchanged in the urine, with a half-life of 21 hours.

Vitamin E is an antioxidant for the maintenance of good health. It is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Pisum sativium L. (Green pea) has immune system effects and contains approximately 25 % crude protein. After oral administration, pea protein is broken down by the acid and pepsin in the stomach and further broken down in the small intestine to amino acids and small peptides which are systemically absorbed.

Spinacia oleracea L. (Spinach) contains various nutrients, including vitamin C, vitamin E, vitamin K, B vitamins, magnesium, iron, calcium,

beta-carotene, folic acid and oxalic acid. The iron and calcium in spinach are poorly absorbed after oral intake and oxalates are excreted in the urine.

Zingiber officinale Roscoe (Ginger) contains active constituents such as gingerol, gingerdione, shogaol and monoterpene volatile oils which has antioxidant and immunomodulating effects.

Inositol is an essential component of cell membrane phospholipids and has a variety of stereoisomers, including myo-inositol and D-chiro-inositol. Oral inositol is absorbed almost completely and is metabolised by myo-inositol oxidase.

Copper helps to produce and repair connective tissue and to form red blood cells. It is absorbed primarily from the small intestines, mainly distributed to the skeleton and muscles and excreted in the urine.

Niacinamide (vitamin B_3) is a water-soluble vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is rapidly absorbed from the gastrointestinal tract and is excreted mainly via urine.

Alpha Lipoic Acid provides antioxidants for the maintenance of good health and helps to promote healthy glucose metabolism. It is readily absorbed from the gut, extensively metabolised in the liver to dihydrolipoic acid (DHLA) and excreted in the urine.

Manganese is an essential nutrient that is involved with normal cell growth and generation of the immune response. It is not well absorbed and is cleared hepatically.

Coenzyme Q10 (Ubidecarenone) is a fat-soluble compound that acts like a vitamin. It is a large molecule that is poorly absorbed when taken orally and has a half-life of approximately 34 hours.

Pyridoxine (vitamin B_6) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. It is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Malpighia glabra L. (Acerola)fruit is a rich source of vitamin C which is more bioavailable when ingested in Acerola than when taken as an ascorbic acid dietary supplement. It also contains numerous minerals and other vitamins and has antioxidant effects.

Oryza sativa L. (Rice bran) contains fiber, lipids, amino acids and a variety of vitamins and minerals. Most of the fiber in Rice bran is insoluble.

Rosa canina L. (Rose hip) contains vitamin C which has antioxidant effects.

Thiamine (vitamin B_1) is a water-soluble B-vitamin that helps to metabolise carbohydrates, fats and proteins and contributes to normal growth. It is absorbed at the proximal part of the small intestines. It occurs in the body as the metabolically active form, thiamine diphosphate, and is excreted in the urine.

Riboflavin (vitamin B_2) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. Oral supplementation results in the production of 7-hydroxymethylriboflavin in blood plasma and is excreted in the urine.

Acacia gum is an indigestible, water-soluble dietary fiber. It is not absorbed from the gastrointestinal tract and passes unchanged through the small intestine. It is fermented to short-chain fatty acids by bacteria in the large intestine.

Larch Arabinogalactan has immune-boosting properties. It is resistant to digestion in the stomach and small intestine and is instead fermented by human colonic microflora to produce acetate, butyrate and propionate.

When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool weight and decreases gastrointestinal (GI) transit time.

Aloe vera (L.) Burm.f. (Aloe) has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

Selenium is a mineral with antioxidant properties for the maintenance of good health. The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase. It is excreted mainly in the urine.

Vanadium is a trace mineral that is factor in the maintenance of good health. Only about 5 % is absorbed with highest concentrations found in the liver, kidneys and bone. Vanadium is excreted primarily in the urine.

Chromium is a mineral that has antioxidant properties and helps to support healthy glucose metabolsim. The small percentage of chromium that is absorbed, approximately 0,5 % to 2 %, is rapidly excreted in the urine and unabsorbed chromium in the faeces.

Iodine contributes to the normal production of the thyroid hormones and normal thyroid function. It is absorbed through the stomach and duodenum and is converted to iodide. Iodine is excreted mainly in the urine, with small amounts excreted in faeces, sweat and saliva.

Molybdenum is an essential trace mineral that helps the body to metabolise proteins. It is readily absorbed from the gastrointestinal tract and is mainly excreted in the urine.

Vitamin A is a fat-soluble vitamin that contributes to immune function. It is readily absorbed from the gastrointestinal tract and is excreted primarily in the urine.

Folic acid is a water-soluble vitamin that helps the body to metabolise proteins and form red blood cells. After absorption, it is reduced to tetrahydrofolate and then converted to L-methylfolate. It is excreted mainly in the urine.

Biotin is an essential, water-soluble B vitamin that helps to metabolise carbohydrates, fats and proteins. It is completely absorbed after oral administration. Biotin metabolites are formed by beta-oxidation, sulfur oxidation, or both, and is excreted in the urine.

Cyanocobalamin (vitamin B_{12}) is an essential water-soluble vitamin that contributes to normal red blood cell formation. It is absorbed in the terminal ileum and has a half-life of about 25 – 30 hours.

Cholecalciferol (vitamin D_3) is a fat-soluble vitamin that helps in the development and maintenance of bones and teeth and helps with the absorption and use of calcium and phosphorous. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Glycine is an amino acid involved in muscle protein synthesis. It is rapidly absorbed in the blood and is eliminated within hours after ingestion.

L-methionine is an essential amino acid for the maintenance of good health.

Nasturtium officinale R.Br (Watercress) has antioxidant effects and is excreted in the urine.

Lecithin is a phospholipid mixture that can be hydrolysed in the gut by phospholipase A and lecithin intake can increase choline levels within one hour of ingestion.

Citrus x aurantium L. (Orange) has antioxidant effects.

Soy protein is isolated from the bean of soy (Glycine max L.). Soybeans are legumes that contain up to 50 % protein. The soy isoflavones, genistein and daidzein, are hydrolysed by beta-glucosidases in the jejunum and are primarily excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium (E468)
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Pharmaceutical glaze [containing shellac resin (E904)]
Silicon dioxide (E551)
Stearic acid (E570).

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 inner seal is missing or broken.

6.5 Nature and contents of container

HDPE container with a ribbed polypropylene cap containing 120 tablets and a white cotton wad.

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.

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